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(54) Title: SYRINGE PLUNGER LOCKING MECHANISM

(57) Abstract: A injection system having a syringe body which defines a pumping chamber. A syringe plunger is located in the pumping chamber and is adapted for reciprocal motion within the pumping chamber. The syringe plunger includes a capture member projecting outwardly in a proximal direction. An actuating shaft is coupled to the syringe plunger and is movable through the syringe body to control movement of the syringe plunger. The capture member is adapted to flex radially outwardly when contacted by the actuating shaft to form a releasable engagement with the actuating shaft when the actuating shaft and the capture member are in an engagement position. A release actuator is disposed proximal to the syringe body, and the capture member releases the actuating shaft upon engagement with the release actuator.

SYRINGE PLUNGER LOCKING MECHANISM

FIELD OF THE INVENTION

The present invention relates to angiography and more specifically, injectors used to inject a medical fluid such as radiographic material into living organisms.

BACKGROUND OF THE INVENTION

One of the major systems in the human body is the circulatory system. The major components of the circulatory system are the heart, blood vessels, and the blood, all of which are vital to the transportation of materials between the external environment and the different cells and tissues of the human body.

The blood vessels are the network of passageways through which the blood travels in the human body. Specifically, arteries carry the oxygenated blood away from the left ventricle of the heart. These arteries are aligned in progressively decreasing diameter and pressure capability from the aorta, which carries the blood immediately out of the heart to other major arteries, to smaller arteries, to arterioles, and finally to tiny capillaries, which feed the cells and tissues of the human body. Similarly, veins carry the oxygen-depleted blood back to the right atrium of the heart using a progressively increasing diameter network of venules and veins.

If the heart chambers, valves, arteries, veins or other capillaries connected thereto are either abnormal (such as from a birth defect), restricted (such as from atherosclerotic plaque buildup), or deteriorating (such as from aneurysm formation), then a physician may need to examine the heart and connected network of vessels. The physician may also need to correct any problems encountered during the examination with a catheter or similar medical instrument.

Angiography is a procedure used in the detection and treatment of abnormalities or restrictions in blood vessels. During angiography, a radiographic image of a vascular structure is obtained by injecting radiographic contrast material through a catheter into a vein or artery. The vascular structures fluidly connected with the vein or artery in which the injection occurred are filled with contrast material. X-rays are passed through the region of the body in which the contrast, material was injected. The X-rays are absorbed by the contrast material, causing a radiographic outline or image of the blood vessel containing the contrast material. The x-ray images of the blood vessels filled with contrast material are usually recorded onto film or videotape and are displayed on a fluoroscope monitor.

Angiography gives the doctor an image of the vascular structures in question. This image may be used solely for diagnostic purposes, or the image may be used during a

procedure such as angioplasty where a balloon is inserted into the vascular system and inflated to open a stenosis caused by atherosclerotic plaque buildup.

Currently, during angiography, after a physician places a catheter into a vein or artery (by direct insertion into the vessel or through a skin puncture site), the angiographic catheter is connected to either a manual or an automatic contrast injection mechanism.

A simple manual contrast injection mechanism typically has a syringe and a catheter connection. The syringe includes a chamber with a plunger therein. Radiographic contrast material is suctioned into the chamber. Any air is removed by actuating the plunger while the catheter connection is facing upward so that any air, which floats on the radiographic contrast material, is ejected from the chamber into the air. The catheter connection is then attached to a catheter that is positioned in a vein or artery in the patient.

The plunger is manually actuated to eject the radiographic contrast material from the chamber, through the catheter, and into a vein or artery. The user of the manual contrast injection mechanism may adjust the rate and volume of injection by altering the manual actuation force applied to the plunger.

Often, more than one type of fluid injection is desired, such as a saline flush followed by the radiographic contrast material. One of the most common manual injection mechanisms used today includes a valve mechanism which controls which of the fluids will flow into the valving mechanism and out to the catheter within the patient. The valve mechanism contains a plurality of manual valves that the user operates manually to open and close that particular fluid channel. When the user suctions or injects contrast fluid into the chamber, the fluid is pulled from the valve mechanism via the open valves. By changing the valve positions, another fluid may be injected.

These manual injection mechanisms are typically hand actuated. This allows user control over the quantity and pressure of the injection. However, all of the manual systems are only capable of injecting the radiographic contrast material at maximum pressure that can be applied by the human hand (i.e., 150 p.s.i). Also, the quantity of radiographic contrast material is typically limited to a maximum of about 12cc. Finally, there are no safety limits on these manual contrast injection mechanisms which act to restrict or stop injections that are outside of reasonable parameters (such as rate or pressure) and no active sensors to detect air bubbles or other hazards.

Currently used motorized injection devices consist of a syringe connected to a linear actuator. The linear actuator is connected to a motor, which is controlled electronically. The operator enters into the electronic control a fixed volume of contrast material to be injected at

a fixed rate of injection. The fixed rate of injection consists of a specified initial rate of flow increase and a final rate of injection until the entire volume of contrast material is injected. There is no interactive control between the operator and machine, except to start or stop the injection. Any change in flow rate must occur by stopping the machine and resetting the parameters.

The lack of ability to vary the rate of injection during the injection results in suboptimal quality of angiographic studies. This is because the optimal flow rate of injections varies considerably between patients. In the cardiovascular system, the rate and volume of contrast injection is dependent on the size of and blood flow rate within the chamber or blood vessel being injected. In many or most cases, these parameters are not known precisely. Moreover, the optimal rate of injection can change rapidly, as the patient's condition changes in response to drugs, illness, or normal physiology. Consequently, the initial injection of contrast material may be insufficient in flow rate to outline the structure on x-ray imaging, necessitating another injection. Conversely, an excessive flow rate might injure the chamber or blood vessel being injected, cause the catheter to be displaced (from the jet of contrast material exiting the catheter tip), or lead to toxic effects from contrast overdose (such as abnormal heart rhythm).

Furthermore, the linear actuator is usually connected to the plunger by a "snap fit" arrangement wherein automatic engagement and disengagement of the plunger with the linear actuator is desirable to prevent contamination of the pumping chamber of the syringe and to simplify the operation of the injection system. In some situations, it is desirable to damage or destroy the connection portion of the plunger to prevent reuse of the syringe. As a result, particulates may remain in the connection area and cause problems during subsequent interconnections.

Another problem often encountered when providing a syringe plunger arrangement which automatically engages and disengages with the linear actuator is that the force necessary for engagement is too high, while the force necessary for disengagement is too low. With such an arrangement, it may be difficult to maintain the plunger in a fixed position relative to the pumping chamber because the plunger may be driven forward during the engagement procedure, and it may be difficult to maintain the plunger in an engaged position with the linear actuator when the linear actuator is retracted.

At present, the operator can choose between two systems for injecting contrast material: a manual injection system which allows for a variable, operator interactive flow rate

of limited flow rate and a preprogrammed motorized system without operator interactive feedback (other than the operator can start/stop the procedure).

SUMMARY OF THE INVENTION

The present invention provides a number of devices and methods for releasably connecting a syringe plunger to a drive member of an angiographic injector of a type having a syringe holder. A syringe includes a syringe body having a distal end and a proximal end, and the syringe body defines a pumping chamber. The syringe plunger is located in the pumping chamber and is adapted for reciprocal motion. An actuating shaft is coupled to the syringe plunger and is movable through the syringe body to control movement.

In one embodiment of the present invention, a syringe plunger includes a capture member projecting outwardly in a proximal direction, while an actuating shaft includes a circumferential groove. A latch is disposed on an inner surface of the capture member, and a finger extends radially outwardly from the capture member. During the connecting procedure, the actuating shaft is driven forward to contact the syringe plunger, and the capture member flexes radially outwardly and engages with the circumferential groove to form a releasable connection. A release actuator is disposed proximal to the syringe body. The release actuator may be a plate defining an aperture for allowing manipulation of the syringe plunger. During the disconnecting procedure, the syringe plunger is retracted such that the finger abuts against an inner surface of the plate and causes the capture member to flex radially outwardly. The latch disengages with the circumferential groove and the syringe is disconnected from the actuating shaft. In the exemplary embodiment, the capture members are designed to permanently deform during the disconnecting procedure to ensure that the syringe is disposed of after use with one patient and not accidentally re-used on a new, different patient.

In another embodiment of the present invention, a syringe plunger includes a circumferential groove, and an actuating shaft includes a pivot member for capturing the syringe plunger. The pivot member is disposed at a distal portion of an actuating shaft. A distal portion of the pivot member includes a latch projecting outwardly from an inner surface thereof, and a proximal portion of the pivot member includes a ramped lug projecting outwardly from an outer surface thereof. A release actuator may be a plate located proximal to the syringe body defining an aperture for allowing manipulation of the syringe plunger. During the connecting procedure, the actuating shaft is driven forward to contact the syringe plunger, the distal portion of the pivot member projects radially outwardly, and the latch engages with the circumferential groove to form a releasable connection. During the

disconnecting procedure, the syringe plunger is retracted such that the ramped lug slidingly engages with a sidewall of the aperture. The proximal end of the pivot member is driven radially inwardly and the distal end of the pivot member is projected radially outwardly such that the latch disengages with the circumferential groove.

In another embodiment, a syringe plunger is magnetically connected to an actuating shaft. The syringe plunger includes a first insert comprising a ferrous metal, permanent magnet, or electromagnet, while the actuating shaft includes a second insert comprising a ferrous metal, permanent magnet, or electromagnet. Any combination of ferrous metal, permanent magnet or electromagnet may be used when configuring the first and second insert as long as a permanent magnet or electromagnet is included in one of the inserts. During the connecting procedure, the actuating shaft is driven forward to contact the syringe plunger, and the syringe plunger remains magnetically attached to the actuating shaft. One of the benefits of utilizing a magnetic syringe plunger arrangement is that a "zero" engagement force is required. As described in the previous embodiment, a release actuator is disposed proximal to the syringe body. The release actuator may be a plate located proximal to the syringe body, and the plate defines an aperture for allowing manipulation of the syringe plunger. The syringe plunger further includes a base having an outer diameter larger than the aperture of the plate. During the disconnecting procedure, the syringe plunger is retracted until the base abuts against an inner surface of the plate. Upon further retraction, the plunger disengages from the actuating shaft.

In another embodiment, a syringe plunger is attached to an actuator having a split collet actuator head. The syringe plunger includes a plunger support member having a receiving aperture formed therein, and at least one retaining member located thereon. The split collet actuator head comprises an alignment shaft positioned between a first collet member and a second collet member. The individual collet members have flange portions formed thereon. Biasing members are positioned between the first and second collet members and bias the collet members outwardly. During the connecting procedure, the actuating shaft is driven forward to contact the syringe plunger, wherein the first and second collet members are forced inwardly. Thereafter, the at least one retaining member engages the individual flange members formed on the collet members and the biasing members force the first and second collet members outwardly. Thereafter, the syringe plunger is coupled to the actuating shaft.

To detach the syringe plunger from the actuator the actuator is retracted to a position proximal the rear plate of the syringe holder assembly. During the retraction procedure, the

detachment members located on the first and second collet members are caused to engage the rear plate of the syringe holder assembly. As a result, the first and second collet members are forced inwardly and the at least one retaining member disengages the flange portion. Upon further retraction, the plunger disengages from the actuating shaft.

Other objects, features, and advantages of the present invention will become apparent from a consideration of the following detailed description and from the accompanying descriptions.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view illustrating a preferred embodiment of the angiographic injector system in accordance with the present invention.

FIGS. 2A-2G are diagrams illustrating operations of the system of FIG. 1.

FIG. 3 is an electrical block diagram of the control system of the injector system of FIG. 1.

FIG. 4 illustrates front panel controls and displays of a preferred embodiment of the injector system in accordance with the present invention.

FIGS. 5A and 5B are side and partial top perspective views of the remote control of the system of FIG. 1.

FIG. 6 is a perspective view of a foot operated remote control.

FIGS. 7A-7D illustrate the operation of the inlet check valve and manifold during contrast fill, air purge, and patient inject operations.

FIGS. 8A-8C illustrate operation of the inlet check valve in greater detail.

FIG. 9 shows a conventional syringe body adapted for dual port.

FIG. 10 is a perspective view of an adapter insert used in the dual port syringe of FIG. 9.

FIGS. 11A-11B are top and side views of the adapter insert of FIG. 10.

FIG. 12 is a perspective view of one embodiment of a syringe usable in the angiographic injector system, according to the present invention.

FIG. 13 is a bottom plan view of the syringe depicted in FIG. 12.

FIG. 14 is a top plan view of the syringe depicted in FIG. 12.

FIG. 15 is a side elevational view of the syringe depicted in FIG. 12.

FIG. 16 is a front side elevational view of the syringe depicted in FIG. 12.

FIG. 17 is a rear side elevational view of the syringe depicted in FIG. 12, and without the plunger therein.

FIG. 18 is a perspective view of one embodiment of a syringe holder arrangement, according to the present invention.

FIG. 19 is a perspective view of the syringe holder arrangement depicted in FIG. 18, and holding a syringe and a bottle of fluid.

FIG. 20 is an exploded, perspective view of a subassembly of the syringe holder arrangement depicted in FIG. 18.

FIG. 21 is a rear side elevational view of the syringe depicted in FIG. 12, and analogous to FIG. 17, but with the plunger therein.

FIG. 22 is a schematic, side elevational view of an air column detector and tubing, in accordance with the present invention.

FIG. 23 is a side plan view of a drive piston and an actuator head for the injector systems of FIGS. 1 and 18 in accordance with the present invention, wherein the drive piston is coupled to the actuator head by flexible capture members.

FIG. 24A is a perspective view of a syringe plunger for the drive piston and actuator head of FIG. 23.

FIG. 24B is a cross sectional side view of the syringe plunger shown in FIG. 24A.

FIG. 24C is a plan bottom view of the syringe plunger shown in FIG. 24A.

FIG. 25 is a plan side view of another embodiment of a syringe plunger arrangement for the injector systems of FIGS. 1 and 18 in accordance with the present invention, wherein a syringe plunger is magnetically coupled to an actuator.

FIG. 26 is a plan side view of another embodiment of a syringe plunger arrangement for the injector systems of FIGS. 1 and 18 in accordance with the present invention, wherein a syringe plunger is coupled to an actuator by pivoting members.

FIGS. 27A-27G illustrate another embodiment of a syringe plunger arrangement for the injector systems in accordance with the present invention, wherein a syringe plunger is coupled to an actuator by a tongue and groove system.

FIG. 28 is a plan side view of another embodiment of a syringe plunger arrangement for the injector systems of FIGS. 1 and 18 in accordance with the present invention, wherein a syringe plunger is coupled to an actuator by pivoting members.

FIGS. 29A–29B illustrate another embodiment of a syringe plunger arrangement for the injector systems of FIGS. 1 and 18 in accordance with the present invention, wherein a retainer ring maintains a syringe plunger in a fixed position during engagement.

FIG. 30 illustrates a still further embodiment of a syringe plunger arrangement for the injector systems of FIGS. 1 and 18 in accordance with the present invention, wherein a syringe plunger is coupled to an actuator by a "Christmas tree" type fastener.

FIG. 31A-31M illustrate yet another embodiment of a syringe plunger arrangement for injector systems in accordance with the present invention, wherein the syringe plunger is coupled to an actuator having a split collet design.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As used herein to describe the angiographic injection system of the present invention, the terms "axial" or "axially" refer generally to an axis A around which the system is formed. The terms "proximal" or "rearward" refer generally to an axial direction toward the end of injector housing opposite the main console. The terms "distal" or "forward" refer generally to an axial direction towards a syringe tip. The term "radial" refers generally to a direction normal to axis A.

EXEMPLARY ANGIOGRAPHIC INJECTOR SYSTEM

FIG. 1 shows angiographic injector system 10 for injecting radiographic contrast material into a blood vessel under interactive physician control. System 10 includes main console 12, hand held remote control 14, syringe holder 16, syringe body 18, syringe plunger 20, radiographic material reservoir (bottle) 22, one-way valve 24, manifold 26, high pressure tube 28, catheter 30, patient medication port 32, three-way stop-cock 34, T-connector 36, pressure transducer 38, stop-cock 40, tubing 42, peristaltic pump 44, saline check valve 46, waste check valve 48, saline bag 50, waste bag 52, and bag support rack 54.

Console 12 houses the electrical controls for system 10, together with the motors which drive piston 20 and peristaltic pump 44. On the front surface of console 12, user interface 54 provides control switches 56 and display 58 through which the user may enter control settings and monitor the operational state of system 10.

Remote control 14 is connected to console 12 by cable 60 (although in other embodiments remote control 14 may be connected by a wireless connection such as a RF, infrared optic, or ultrasonic link). Remote control 14 is, in the embodiment shown in FIG. 1, a hand-held control which includes reset and saline push button switches 62 and 64, respectively, and flow rate control lever or trigger 66. By squeezing trigger 66, the user can provide a command signal to console 12 to provide a continuously variable injection rate.

Syringe holder 16 projects from the left hand side of console 12. Syringe holder 16 is preferably a clear material, and includes a half cylindrical back shell 68, a half cylindrical front door 70 (which is shown in open position in FIG. 1), and reservoir holder 72.

Syringe 18 is a transparent or translucent plastic cylinder having its open end 74 connected to console 12. Closed end 76 of syringe 18 contains two ports: upper port 78 and lower port 80.

Plunger 20 is movable within syringe body 18. Plunger 20 is connected to, and driven by a motor located within console 12.

Radiographic contrast material reservoir 22 is connected through one-way check valve 24 to upper port 78. Radiographic contrast material is drawn from reservoir 22 through check valve 24 and upper port 78 into the pumping chamber defined by syringe body 18 and plunger 20. Check valve 24 is preferably a weighted one-way valve which permits air to flow from syringe body 18 back into reservoir 22, but will not permit radiographic contrast material to flow from syringe body 18 to reservoir 22. This permits automatic purging of air from the system, as will be described in more detail later.

Lower port 80 of syringe body 18 is connected to manifold 26. Manifold 26 includes a spring biased spool valve which normally connects transducer/saline port 82 and patient port 84. When radiographic contrast material is to be injected, the pressure of the radiographic material causes the spool valve to change states so that lower port 80 is connected to patient port 84.

High pressure tube 28 is a flexible tube which connects patient port 84 to catheter 30. Three-way stop-cock 34 is located at the distal end of tube 28. Rotatable luer lock connector 86 is connected to stop-cock 34 and mates with luer connector 88 at the proximal end of catheter 30. Stopcock 34 either blocks flow between tube 28 and catheter 30, permits flow, or connects medication port 32 to catheter 30.

In addition to injecting radiographic material into a patient through catheter 30, system 10 also permits other related functions to be performed. A device for delivering the patient medication (not shown in FIG. 1) may be connected to medication port 32 when medication is to be delivered through catheter 30 to the patient.

When catheter 30 is in place in the patient, and an injection of radiographic contrast material is not taking place, pressure transducer 38 monitors the blood pressure through the column of fluid which extends from catheter 30, tube 28, patient port 84, manifold 26, transducer/saline port 82, tubing 90, T-connector 36, and tubing 92. Transducer 38 has an associated stop-cock 40 which allows transducer 38 to be exposed to atmospheric pressure during calibration and also allows for removal/expulsion of trapped air so the dome chamber of transducer 38 can be flushed with saline.

Peristaltic pump 44 supplies saline solution from bag 50 through saline check valve 46, tubing 42, T-connector 36 and tubing 90 to saline port 82. When peristaltic pump 44 is operating to supply saline solution, the saline solution is supplied through manifold 26 to patient port 84 and then through tube 28 to catheter 30.

Peristaltic pump 44 also operates in an opposite direction to draw fluid from catheter 30 and through tube 28, manifold 26, tubing 90, T-connector 36 and tubing 42 to waste check valve 48 and then into waste collection bag 52.

In one embodiment of the present invention, syringe body 18, manifold 26, tube 28, catheter 30, T-connector 36, tubing 42, check valves 46 and 48, bags 50 and 52, and tubing 90 and 92 are all disposable items. They must be installed in system 10 each time an angiography procedure is to be performed with a new patient. Once system 10 is set up with all the disposable items installed, door 70 is closed, and syringe body 18 filled with contrast material and purged of air, the user (typically a physician) enters into system 10 the safety parameters that will apply to the injection of radiographic contrast material. These safety parameters typically include the maximum amount of radiographic contrast material to be injected during any one injection, the maximum flow rate of the injection, the maximum pressure developed within syringe body 18, and the maximum rise time or acceleration of the injection. To actuate an injection of contrast material, the user operates remote control 14 by squeezing trigger 66. Within the preset safety parameters, system 10 causes the flow rate of the injection to increase as the force or distance of travel of trigger 66 is increased.

Typically, the user will meter the amount and rate of contrast material injected based upon continuous observation of the contrast outflow into the structure being injected using fluoroscopy or other imaging methods. System 10 allows the user to tailor the contrast injections to the needs of the patient, thereby maximizing the quality of the procedure, increasing the safety, and reducing the amount of contrast material required to perform the fluoroscopic examination.

FIGS. 2A-2G are diagrams illustrating fluid flow paths during seven different operations of system 10. Those operations are contrast fill (FIG. 2A), air purge (FIG. 2B), patient inject (FIG. 2C), patient pressure (FIG. 2D), saline flush (FIG. 2E), aspirate waste (FIG. 2F), and medicate patient (FIG. 2G).

The contrast fill operation illustrated in FIG. 2A involves the filling of syringe body 18 with radiographic contrast material from reservoir (contrast media supply) 22. The contrast fill operation is performed during initial set up of system 10, and may be repeated

during operation of system 10 whenever syringe body 18 is running low on radiographic contrast material.

During initial set up of system 10, plunger 20 is initially driven to a forward position approximately 20% from closed end 76 of syringe body 18. In other words, plunger 20 is driven forward to a position which corresponds to approximately 80% of the length of the syringe. This will expel to the atmosphere a portion of the air which is located within syringe body 18.

Plunger 20 is then retracted, which creates a vacuum within syringe body 18 which draws contrast material from reservoir 22 through check valve 24 into syringe body 18 through upper port 78. If it is desirable to transfer additional contrast material into syringe body 18, a "sipping" procedure may be implemented where the process of driving plunger 20 approximately 20% from closed end 76 and retracting plunger 20 is repeated.

The Contrast Fill operation typically will result in some air being drawn into or remaining within syringe body 18. It is important, of course, to prevent air from being injected into the patient through catheter 30. That is the purpose of the Air Purge operation shown in FIG. 2B. Also, the location of two ports at different elevations allows for a greater amount of safety in preventing air bubbles in the injection.

During the Air Purge operation, plunger 20 travels forward to expel trapped air within syringe body 18. The air, being lighter than the contrast material, gathers near the top of syringe body 18. As plunger 20 moves forward, the air is expelled from syringe body 18 through upper port 78 and one-way valve 24. In the embodiment illustrated in FIG. 2B, one-way valve 24 is a weighted one-way valve which allows flow of radiographic contrast material from reservoir 22 to upper port 78, but will not allow radiographic contrast material to flow in the opposite direction from upper port 78 to reservoir 22. Valve 24 will, however, allow air to flow from port 78 to reservoir 22. As soon as radiographic contrast material begins flowing out of syringe body 18 through upper port 78 to valve 24, valve 24 closes to prevent any further flow toward reservoir 22.

Valve 24 can also, in alternative embodiments, can be a solenoid actuated or motor driven valve operated under control of the electric circuitry within console 12. In either case, valve 24 is capable to withstanding the relatively high pressures to which it will be subjected during the inject operation. Preferably, valve 24 is capable of withstanding static fluid pressures up to about 1200 p.s.i.

FIG. 2C illustrates the Patient Inject operation. Plunger 20 travels forward under the interactive control of the user, who is controlling trigger 66 of remote control 14. The

movement of plunger 20 creates hydraulic pressure to force contrast material out of syringe body 18 through lower port 80 and through manifold 26 and high pressure tube 28 into catheter 30. As shown in FIG. 2C, syringe lower port 80 and patient port 84 are connected for fluid flow during the patient inject operation.

Manifold 26 contains a valve which controls the routing of fluid connections between patient port 84 and either syringe bottom port 80 or transducer/saline port 82. In one embodiment of the invention, manifold 26 includes a spool valve which is spring biased so that patient port 84 is normally connected to transducer/saline port 82 (as illustrated in FIGS. 2A and 2B). When the pressure at syringe bottom port 80 builds with the movement of plunger 20 forward, the bias force against the spool valve is overcome so that syringe bottom port 80 is connected to patient port 84, and transducer/saline port 82 is disconnected the valve within manifold 26 protects pressure transducer 38 from being exposed to the high pressure generated by the patient inject operation.

The spool valve opens automatically during the patient inject operation in response to increase pressure exerted on it from the syringe lower port 80. The spool valve closes and returns to its original position allowing for connection of patient port 84 to transducer 38 when a slight vacuum is applied by retraction of plunger 20 at the end of each Patient Inject operation.

In an alternative embodiment, the valve within manifold 26 is an electromechanical or motor driven valve which is actuated at appropriate times to connect either syringe lower port 80 or transducer/saline port 82 to patient port 84. The actuator mechanism is controlled by console 12. Once again in this alternative embodiment, the valve protects pressure transducer 38 from being exposed to high pressure.

FIG. 2D illustrates the Patient Pressure operation. System 10 allows for reading of the patient's blood pressure, which is monitored through catheter 30. Patient blood pressure can be monitored through the use of pressure transducer 38 at any time except during the patient inject, saline flush, and waste aspirate operations. The pressure reading being produced by pressure transducer 38 may be normalized by manually opening stop-cock 40 and closing stop-cock 34 to expose pressure transducer 38 to atmospheric pressure.

During the Saline Flush operation illustrated in. FIG. 2E, saline solution is used to flush all of the internal lines, pressure transducer chamber 38, tube 28, and catheter 30. As shown in FIG. 2E, peristaltic pump 44 is operating in a direction which causes saline solution to be drawn from bag 50 through check valve 46 and through tubing 42 to saline port 82.

Manifold 26 connects saline port 82 to patient port 84 so that saline solution is pumped out of patient port 84 and through tube 28 and catheter 30.

During the Aspirate Waste operation, patient port 84 is again connected to saline port 82. During this operation, peristaltic pump 44 is operating in the opposite direction from its rotation during the saline flush operation. As a result, patient fluids are aspirated from patient port 84 to saline port 82 and then through tubing 42 and check valve 48 into waste collection bag 52. Peristaltic pump 44 acts as a valve pinching/occluding tubing 42 and preventing back flow to/from saline and waste containers 50 and 52 in conjunction with check valves 46 and 48.

With catheter 30 in place within the patient, it may be desirable to supply patient medication. System 10 allows for that option by providing patient medication port 32. As shown in FIG. 2G, when stop-cock 34 is open, a medication source connected to port 32 will be connected to patient port 84, and thereby to catheter 30. During the medicate patient operation, peristaltic pump 44 and plunger 20 are not moving.

FIG. 3 is an electrical block diagram of the control system which controls the operation of angiographic injector system 10. The electrical control system includes digital computer 100, which receives input signals from remote control 14 and front panel controls 56 through interface 102, and provides signals to display 58 to display operation data, alerts, status information and operator prompts.

Computer 100 controls the motion of plunger 20 through a motor drive circuit which includes motor 104, motor amplifier 106, tachometer 108, potentiometer 110, a rectifier 112, pressure sensing load cell 114, and A/D converter 160.

Motor amplifier 106 provides a drive signal to motor 104 in response to Control Voltage, Fwd/Rev, and/Brake signals from computer 100 and a speed feedback signal from tachometer 108 through rectifier 112. The outputs of tachometer 108 and potentiometer 110 are supplied to computer 100 through A/D converter 116 as Speed Monitor and Position Monitor signals. These allow computer 100 to check motor speed, motor direction, and position (volume is a calculated value).

Pressure sensor 114 senses motor current or plunger force in order to measure the pressure being applied to the radiographic contrast material within syringe body 18. This Pressure Monitor Signal is supplied through A/D converter 116 and interface 102 to computer 100.

Peristaltic pump 44 is driven under the control of computer 100 through pump motor 120, motor driver 122 and optical encoder 124. Computer 100 provides Saline (Forward) and

Waste (Reverse) drive signals to motor driver 122 to operate pump motor 120 in a forward direction for saline flush and a reverse direction for waste aspiration. Optical encoder 124 provides the Speed Direction Monitor signal to interface 102 which indicates both the speed and the direction of rotation of pump motor 120.

FIG. 3 illustrates an embodiment of the control system in which valve motor 130 is used to actuate valves such as one-way valve 24 and the valve within manifold 26. In this embodiment, computer 100 controls valve motor 130 through motor driver 132, and monitors position through a Position Monitor feedback signal from potentiometer 134. In this particular embodiment, valve motor 130 is a stepper motor.

Computer 100 monitors temperature of the contrast material based upon a Temp Monitor signal from temperature sensor 140. Temperature sensor 140 is preferably positioned near syringe body 18. If the temperature being sensed by temperature sensor 140 is too high, computer 100 will disable operation motor 104 to discontinue patient injection. If the temperature is too low, computer 100 provides a /Temp Enable drive signal to heater drive 150, which energizes heater 152. In one preferred embodiment, heater 152 is a resistive film heater which is positioned within syringe holder 116 adjacent to syringe body 18.

Computer 100 also receives feedback signals from contrast bottle sensor 160, forward limit sensor 162, reverse limit sensor 164, syringe missing sensor 166, chamber open sensor 168, no contrast bubble detector 170, and air in line bubble detector 172.

Contrast bottle sensor 160 is a miniature switch located within reservoir holder 72. The state of the Contrast Bottle Present signal from sensor 160 indicates whether a reservoir 22 is in position within holder 72. If reservoir 22 is not present, computer 100 will disable the fill operation.

Forward limit and reverse limit sensors 162 sense the end limit positions of plunger 20. When plunger 20 reaches its forward limit position, no further forward movement of plunger 20 is permitted. Similarly, when reverse limit sensor 164 indicates that plunger 20 has reached its reverse limit position, no further reverse movements are permitted.

Syringe missing sensor 166 is a miniature switch or infrared emitter/detector which indicates when syringe body 18 is not in position within syringe holder 16. If syringe body 18 is not in position, all movement functions are disabled except that plunger 20 can move to its reverse limit position (i.e., return to zero).

Chamber open sensor 168 is a miniature switch or infrared emitter/detector which senses when door 70 of syringe holder 16 is open. When the signal from sensor 168 indicates that door 70 is open, all movement functions are disabled. Only when door 70 is closed and

locked may any movement be allowed. When door 70 is indicated as closed and sensor 166 indicates the syringe body 18 is in position, other normal functions of the system 10 can proceed.

Bubble detector 170 is positioned between reservoir 22 and top port 78, and is preferably an infrared emitter/detector which senses air bubbles. If an air bubble is sensed in the flow path between reservoir 22 and top port 78 during a fill operation, the fill operation is disabled until a new reservoir is connected.

Bubble detector 172 is positioned to sense air bubbles in high pressure line 28. It is preferably an infrared emitter/detector type of bubble detector. Any air bubble which is sensed in high pressure line 28 results in the disabling of all fluid push out functions, whether the fluid is saline solution from peristaltic pump 44 or contrast material from syringe body 18.

The control system of FIG. 3 also includes the capability to provide a control signal to x-ray equipment through relay 180 which is controlled by computer 100. In addition, computer 100 receives data from blood pressure transducer 38 and from an electrocardiograph (ECG) system which is separate from injector system 10. The Pressure and ECG signals are received through signal conditioners and A/D converter 190, and are transferred to computer 100. The ECG signal is used by computer 100 in one preferred embodiment, to synchronize operation of motor 104 (and thus the Patient Inject operation) with heart beats.

Blood flow to the heart occurs predominantly in diastole (when the heart is between contractions). Continuous injection of contrast material results in spillage of the contrast material into the aorta during systole (during contraction). By injecting primarily during diastole, contrast dosage can be reduced without impairing the completeness of the contrast injection into the coronary artery.

In a preferred embodiment, the injection of radiographic contrast material is synchronized to the coronary artery blood flow. The time periods of systole and diastole are determined using an electrocardiographic (ECG) electrical signal, arterial blood pressure waveform analysis, or other timing based on the heart rate. By controlling speed of motor 104, speed and therefore movement of plunger 20, the injection of contrast material is interrupted during the period of systole, which reduces or stops contrast injection during this time. In combination with remote control 14, the operator can vary the rate of contrast injection into the coronary artery while computer 100 automatically pulses the contrast injection to the cardiac cycle.

The inertial forces of the moving contrast material and expansion of the containers and tubing holding the contrast material and transmitting it to the patient can cause a phase lag

between movement of plunger 20 within syringe body 18 and movement of contrast material out of catheter 30 into the patient. To adjust to the phase lag between the plunger 20 movement and contrast expulsion into the patient, a variable time offset can be entered through control panel 54 such that the timing of the cardiac cycle can be offset by a selected time. Since the magnitude of the phase lag may be dependent on the frequency of the heart rate, an algorithm within computer 100 continuously and automatically adjusts the magnitude of the time offset, based on the instantaneous heart rate during the injection of contrast material.

FIG. 4 shows one embodiment of control panel 54 which illustrates the front panel control switches 56 and display 58 of one embodiment of the present invention. Front panel control switches 56 include Set Up/Fill/End switch 200, Purge switch 202, Aspirate switch 204, Saline switch 206, Enable OK switch 208, Injection Volume Limit switches 210a and 210b, Injection Flow Rate Limit switches 212a and 212b, Injection Pressure Limit switches 214a and 214b, Rise Time switches 216a and 216b, OK switch 218, Injection Range Toggle switch 220, Large Injection OK switch 222, and Stop switch 224.

Set Up/Fill/End switch 200 is a momentary, push button switch. When it is first activated, the user will be notified to place syringe 18 in syringe holder 16. When syringe 18 has been placed in syringe holder 16 (which is indicated to computer 100 by sensor 166), the user will be instructed to close and lock the chamber (i.e., to close door 7()). Plunger 20 is moved to a forward position approximately 20% from closed end 76 of syringe body 18. Display 58 then indicates to the operator that contrast reservoir 22 should be connected. Once contrast reservoir 22 has been put in place, the operator is requested to depress OK switch 218, at which time plunger 20 will retract at a set rate (preferably corresponding to a flow rate of 10 ml per second) to the maximum syringe volume. If the real speed (as indicated by feedback to computer 100 from A/D converter 116) is greater than the set speed, system 10 will stop.

Once plunger 20 is at its rearward most position, motor 104 is actuated to move plunger 20 forward to purge all air bubbles. Pressure sensor 114 provides an indication of when one-way valve 24 is closed and pressure is beginning to build up within syringe body 18. Once the purge is completed, the total volume injected and the number of injections counter is reset.

The actuation of switch 200 also allows for full retraction and disengagement of plunger 20 from syringe body 18.

Purge switch 202 is a protected momentary push button switch. When activated, Purge switch 202 causes plunger 20 to move forward to expel air through top port 78. The forward movement of plunger 20 is limited and stopped when a predetermined pressure within syringe 18 is reached. This is sensed by pressure sensor 114. The purge operation which is initiated by Purge switch 202 will expel air within syringe 20. The user may also use Purge switch 202 to purge fluid through patient port 84 by depressing and holding Purge switch 202 continuously on.

Aspirate switch 204 is a momentary push button switch which causes computer 100 to activate pump motor 120 of peristaltic pump 44. Pump motor 120 is operated to aspirate catheter 30 at a set speed, with the aspirated fluid being collected in waste bag 52. All other motion functions are disengaged during aspiration. If the real speed of motor 120 is greater than a set speed, computer 100 will stop motor 120.

Saline switch 206 is an alternate action switch. Pump motor 120 is activated in response to Saline switch 206 being pushed on, and saline solution from bag 50 is introduced into manifold 26 and catheter 30 at a set speed. If Saline switch 206 is not pushed a second time to stop the flow of saline solution within 10 seconds, computer 100 automatically stops pump motor 120. If a time-out is reached, Saline switch 206 must be reset to its original state prior to initiating any further actions.

Enable OK switch 208 is a momentary push button switch. After the system has detected a disabling function at the end of an injection other than a limit, Enable OK switch 208 must be activated prior to activating OK switch 218 and initiating any further function.

Injection Volume Limit keys 210a and 210b are pushed to either increase or decrease the maximum injection volume that the system will inject during any one injection. Key 210a causes an increase in the maximum volume value, and key 210b causes a decrease. Once the maximum injection volume limit has been set, if the measured volume reaches the set value, computer 100 will stop motor 104 and will not restart until OK switch 218 has been depressed. If a large injection (i.e., greater than 10 ml) has been selected, OK switch 218 and Large Injection OK switch 220 must both be reset prior to initiating the large injection.

Injection Flow Rate Limit keys 212a and 212b allow the physician to select the maximum flow rate that the system can reach during any one injection. If the measured rate (which is determined by the feedback signals from tachometer 108 and potentiometer 111) reaches the set value, computer 100 will control motor 104 to limit the flow rate to the set value.

Injection Pressure Limit keys 214a and 214b allow the physician to select the maximum pressure that the system can reach during any one injection. If the measured pressure, as determined by pressure sensor 114, reaches the set value, computer 100 will control motor 104 to limit the pressure to the injection pressure limit. The injection rate will also be limited as a result.

Rise Time keys 216a and 216b allow the physician to select the rise time that the system will allow while changing flow rate during any one injection. Computer 100 controls motor 104 to limit the rise time to the set value.

In alternative embodiments, keys 210a-210b, 212a-212b, 214a-214b, and 216a-216b can be replaced by other devices for selecting numerical values. These include selector dials, numerical keypads, and touch screens.

OK switch 218 is a momentary push button switch which resets functions and hardware sensors. In response to OK switch 218 being activated, computer 100 controls display 58 to ask the operator to acknowledge that the correct function has been selected. Activation of OK switch 218 causes the status to be set to Ready.

Injection Range switch 220 is a toggle switch. Depending on whether switch 220 is in the "small" or "large" position, it selects either a high or a low injection volume range for the next injection.

Large Injection OK switch 222 is a momentary push button switch. When the large injection range has been selected by injection range switch 220, the Large Injection OK button 222 must be activated to enable OK switch 218. OK switch 218 must be activated prior to each injection. On large volume injections, the user is required to verify the volume selected by activating first Large Injection OK switch 222 and then OK switch 218.

Stop switch 224 is a momentary push button switch. When stop switch 224 is pushed, it disables all functions. Display 58 remains active.

Display panel 58 includes Set-Up display 250, Status display 252, Alerts display 254, Limits display 256, total number of injections display 260, total volume injection display 262, flow rate display 264, injection volume display 266, injection volume limit display 268, injection rate limit display 270, pressure limit display 272, rise time minimum display 274, large injection display 276, and real time clock display 278.

Set-Up display 250 contains a series of messages which are displayed as the operator goes through the set up procedure. The display of messages in set up display 250 are initiated by the actuation of set up switch 200 as described previously.

Status display 252 provides a flashing indication of one of several different operating conditions. In the embodiment shown in FIG. 4, these status conditions which can be displayed include "Ready", "Set-Up", "Injecting", "Filling" "Flushing", and "Aspirating".

Alerts display 254 and Limits display 256 notify the operator of conditions in which system 10 has encountered a critical control parameter and will disable operation, or has reached an upper or lower limit and will continue to function in a limited fashion, or has reached an upper or lower limit and will continue to operate.

Total number of injections display 260 displays the total number of injections (cumulative) given for the current patient case. The cumulative total volume injected during the current patient case is displayed by total volume display 262.

Displays 264 and 266 provide information on the current or last injection. Display 264 shows digital value of the real time flow rate to the patient during injection. Once the injection is completed, the value displayed on display 264 represents the peak flow rate reached during that injection. Display 266 shows the digital value of the volume injected during the most recent injection.

Display 268 displays the digital value of the maximum injection volume selected by operation of switches 210a and 210b. Similarly, display 270 shows the digital value of the maximum flow rate that the system will allow, as selected by switches 212a and 212b.

Display 272 shows the digital value of the maximum pressure that the system will allow to be developed in syringe 18. The pressure limit is selected by switches 214a and 214b.

Display 274 displays the minimum rise time that the system will allow while changing flow rate. The minimum rise time is selected through switches 216a and 216b.

Large injection display 276 provides a clear indication when the large injection scale has been selected by the operator.

Real-time clock display 278 shows the current time in hours, minutes, and seconds.

FIGS. 5A and 5B show remote control 14 which includes main housing 300, which is designed to conform to the user's hand. Trigger 66 is movable with respect to housing 300, and the position of trigger 66 generates a command signal which is a function of trigger position. In one embodiment, trigger 66 is linked to a potentiometer within housing 300. The command signal controls the injunction flow rate or speed. The flow rate is directly proportional to trigger position.

Reset switch 62 is a momentary push button switch whose function is identical to that of OK switch 218. Alternatively, Reset switch 62 may also be labeled "OK".

Saline switch 64 on remote control 14 is an alternate action push button switch which is pushed to turn on and pushed again to turn off. The function of Saline switch 62 is the same as that of Saline switch 206 on front panel 54.

As illustrated in another embodiment of the present invention, an alternative remote control 14' in the form of a foot pedal is used instead of the hand held remote control 14 illustrated in FIG. 1 and in FIGS. 5A and 5B. Foot pedal remote control 14' includes foot operated speed pedal or trigger 66' for providing a command signal, as well as Reset or OK switch 62' and Saline switch 64'. Covers 310 and 312 protect switches 62' and 64' so that they can only be actuated by hand and not accidentally by foot. Foot pedal remote control 14' is connected to console 12 by cable 60', but could alternatively be connected by a wireless link.

FIGS. 7A-7D and FIGS. 8A-8C illustrate the construction and operation of one way valve 24 and manifold 26 during Contrast Fill, Air Purge and Patient Injection operation.

FIGS. 7A and 8A illustrate one way or check valve 24, manifold 26, syringe body 18, and plunger 20 during a Contrast Fill operation. Inlet check valve of one way valve 24 includes weighted ball 350 which is positioned at its lower seated position within valve chamber 352 in FIGS. 7A and 7B. Contrast material is being drawn into syringe body 18 by the rearward movement of plunger 20. The contrast material flows through passages 354 around ball 350 and into upper port 78.

Manifold 26 contains spring loaded spool valve 360, which includes spool body 362, shaft 364, O-rings 366, 368 and 370, bias spring 372, and retainer 374. As shown in FIG. 7A, during the Contrast Fill operation, bias spring 372 urges spool body 362 to its right-most position toward syringe body 18. In this position, spool body 362 blocks lower port 80 of syringe body 18 while connecting transducer saline port 82 to patient port 84 through diagonal passage 376. O-rings 366 and 368 on the one hand, and O-ring 370 on the other hand, are positioned on the opposite sides of diagonal passage 376 to provide a fluid seal.

FIGS. 7B and 8B illustrate the Air Purge operation. Syringe body 18 has been filled with contrast fluid, but also contains trapped air. Plunger 20 is driven forward to force the air out of syringe body 18 through upper port 78 and through check valve 24. The force of the air may cause a slight lifting of ball 350 in check valve 20. Ball 350, however, is sufficiently heavy that the air being forced out of syringe body 18 and back toward reservoir 22 cannot lift ball 350 into its uppermost seated position where it would block the flow of air out of syringe body 18.

During the Air Purge operation, spool valve 360 is in the same position as in FIG. 7A. Diagonal passage 376 connects transducer saline port 82 with patient port 84. As a result, pressure monitoring by pressure transducer 38 can be performed during the Air Purge (as well as the Contrast Fill) operation.

FIGS. 7C and 8C illustrate the state of manifold 26 and check valve 24 at the end of the Air Purge operation and at the beginning of a Patient Inject operation.

In FIG. 7C, all air has been expelled from syringe body 18. Ball 350 floats on the radiographic contrast material, so that when all air has been removed and the radiographic contrast material begins to flow out of syringe body 18 and through upper port 78 to valve chamber 352, ball 350 is moved upwards to its upper seated position. Ball 350 blocks any continued upward flow of radiographic contrast material, as is illustrated in FIGS. 7C and 8C.

In the state which is illustrated in FIG. 7C, the pressure within syringe body 18, and specifically the pressure in lower port 80 has not yet reached a level at which the bias force of spring 372 has been overcome. As a result, spool body 362 has not yet moved to the left and diagonal passage 376 continues to connect transducer saline port 82 with patient port 84.

FIG. 7D illustrates the patient inject operation. Plunger 20 is moving forward, and inlet check valve 24 is closed. The pressure at lower port 80 has become sufficiently high to overcome the bias force of spring 372. Spool body 362 has been driven to the left so that lower port 80 is connected to patient port 84. At the same time spool body 362 blocks transducer/saline port 82.

By virtue of the operation of spool valve 360, the high pressure generated by movement of plunger 20 and syringe body 18 is directly connected to patient port 84, while saline port 82 and pressure transducer 38 are protected from the high pressure. The pressure to actuate may be variable and determined after manufacture by increasing or decreasing the syringe preload.

FIGS. 9-11B illustrate another embodiment of the dual port syringe in the present invention. In this embodiment, conventional syringe body 400 is modified to provide dual port functionality. The modification is accomplished by adapter insert 402 and T-connector 404.

Syringe body 400 has a cylindrical side wall 410, frustoconical end wall 412, and tubular end port 414. Adapter insert 402, which is shown in more detail in FIGS. 10 and 11 is inserted into syringe body 400 so that it mates with end wall 412 and tube 414. T-connector 404 connects to the end of tube 414, and provides upper port 420 and lower port 422.

Adapter insert 402 has a frustoconical flange 430 and a generally cylindrical shaft 432. Flange 430 mates against the inner surface of end wall 412 of syringe body 400. Shaft 432 extends through tube 414 and through T-connector 404, so that end surface 434 of shaft 432 is generally located at the distal end of T-connector 404. Upper port groove 436 extends along the upper surface of shaft 432 and the inclined upper surface of flange 430. Upper port groove 436 stops just short of end 434.

Lower port groove 438 extends the entire length of shaft 432, along its lower surface, and then extends downward on the inclined lower surface flange 430.

When adapter insert 402 is positioned within syringe body 400 as shown in FIG. 9, it forms a close press fit with both syringe body 400 and T-connector 404. Upper port groove 436 provides an upper port passage which extends from port 420 to the interior of syringe body 400. As shown in FIG. 9, upper port groove 436 opens into the interior of syringe body 400 at the uppermost portion of the interior.

Lower port groove 438 extends from the distal end of T-connector 404 to the lowermost position in the interior of syringe body 400.

The embodiment of the present invention shown in FIGS. 9-11B provides an inexpensive adaptation of a conventional syringe body so that it can exhibit the advantages of dual port capability.

In conclusion, the angiographic injector system of the present invention provides interactive control of the delivery of radiographic contrast material to a catheter through a user-actuated proportional control. This allows the user to adjust the flow rate of contrast material interactively as needed and as the patient's condition changes.

Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention. For example, syringe holder 16 may take other forms, such as an end loaded cylinder. Similarly, manifold 26 can take other configurations and can incorporate, for example, a part of ports 78 and 80.

ANOTHER EXEMPLARY SYRINGE

FIGS. 12-17 depict one preferred syringe 500 usable in the angiographic system described above. Syringe 500 includes a syringe body 502 having a wall defining first and second opposite ends 504, 506. The first end 504 corresponds to a distal end of syringe 500, and the second end 506 corresponds to a proximal end of syringe 500. The wall of body 502 is cylindrical in the illustrated embodiment and includes a central axis 508 extending longitudinally therethrough.

Syringe body 502 defines a pumping chamber 510 in an interior thereof. A plunger 512 is located in the pumping chamber 510 and is constructed and arranged for reciprocal motion between a position adjacent to first end 504 and second end 506. That is, when syringe 500 is mounted in a system analogous to the angiographic system described herein above, an actuator from the system energizes plunger 512 and causes it to move between the second end 506 and the first end 504. The plunger 512 includes a plunger support member 617 and a cover 618. Plunger support member 617 preferably comprises a rigid, hard material, for example, an ABS plastic, to interface between an actuator and the plunger 512. Member 617 attaches to the actuator by, preferably, a snap fit.

Syringe 500 includes an end wall 514 located at the first end 504 of the syringe body 502. End wall 514 is located generally normal to the central, longitudinal axis 508 of syringe 500. The end wall 514 includes a flat face 516. The flat face 516 is particularly adapted for mating engagement with a syringe holder, to be described further below, in an angiographic system as described above. Flat face 516 is advantageous in the preferred arrangement. In the angiographic system as described herein, significant thrust loads must be borne in order to suitably inject the contrast material into the cardiovascular system of the patient. Flat face 516 allows the thrust load from the injections to be distributed in a manageable fashion. An angled face, in contrast, would create a wedge action, which would unnecessarily stress the syringe and create an unnecessary side load in the syringe holder. The inventors have recognized that a spherical or cone face would require a large door in the syringe holder to support the thrust and would also require some elaborate mechanism to properly position the door against the syringe. Flat face 516 on syringe 500, however, allows the thrust load to be managed by a thin flat door, to be described in more detail below, and is able to bear the thrust load from the angiographic injections.

Syringe 500 defines at least one port for providing fluid flow communication with pumping chamber 510. In the particular embodiment illustrated, syringe 500 includes two ports providing fluid flow communication with the pumping chamber 510. Specifically, an inlet port 518, Fig. 14, allows the pumping chamber 510 in syringe 500 to be filled with contrast material, and purged or air through inlet port 518, allowing for an infinite capacity syringe. By "infinite capacity" it is meant that syringe 500 continues to take in contrast media from a bottle of contrast media, wherein the bottles are replaced when empty. A housing 520 circumscribes inlet port 518 and allows inlet port 518 to be connected with an appropriate bottle 602 of contrast fluid. When syringe 500 is oriented in a syringe holder in an angiographic system as described above, syringe 500 defines a top portion and a bottom

portion. Fig. 15 illustrates the orientation of syringe 500 as it would be mounted in an angiographic system of the preferred embodiment. When in such an orientation, the inlet port 518 is located in the top portion 522 of syringe 500.

In preferred embodiments, the syringe 500 is mounted in an angiographic system such that the syringe 500 angles somewhat from the horizontal. By angling the syringe 500 from the horizontal, air is allowed to gather around the inlet port 518 in order to be expelled through the inlet port 518 during an air purge operation. Angles within the range of about 5-30°, and preferably about 10-15° from the horizontal are preferable.

Inlet housing 520 houses a valve assembly analogous to check valve 24, described and illustrated above. Check valve 24 is competent to fluid, and incompetent to air. That is, check valve 24 permits air to be expelled or purged from the syringe 500, but does not allow fluid to flow out of the pumping chamber 510 and back into the bottle 602 of contrast fluid when pressure movement is applied on the syringe side of the check valve 24.

Syringe 500 also includes an outlet port 524, FIG. 16, in fluid flow communication with pumping chamber 510. Outlet port 524 permits fluid flow from pumping chamber 510 to downstream fluid passageways, and ultimately into the patient's cardiovascular system. Outlet port 524 is surrounded, or circumscribed, by outlet port housing 526 extending, or projecting, from end wall 514. The outlet port housing 526 is adapted, i.e., constructed and arranged, to receive an outlet tube. Outlet port 524 and outlet housing 526 are analogous to lower port 80, described in detail above.

When syringe 500 is oriented in the preferred angiographic system of the present invention, the outlet port 524 is located adjacent to the bottom portion 523 of syringe 500.

The syringe end wall 514 includes an interior portion 528, FIG. 17, and an exterior portion 530, FIG. 14. It is the exterior portion 530 which defines the flat face 516 of syringe 500. The exterior portion 530 includes a plurality of ribs 532. In the embodiment illustrated, there are seven ribs 532 extending transversely across the end wall 514. Ribs 532 help to provide a reinforcing function. Ribs 532 also provide an attractive, ornamental appearance to syringe 500.

Ribs 532 each have end portions 534 terminating in a plane transverse to longitudinal axis 508 of syringe body 502. The end portions 534 define the flat face 516.

The interior portion 528 defines a cone-shaped surface 536, Fig. 17. This cone-shaped surface 536 is illustrated in Fig. 17 by the shading therein. Cone-shaped surface 536 helps to direct the liquid in pumping chamber 510 to an appropriate fluid port.

Preferred dimensions for syringe 500 are described herein below. Syringe body 502 has a diameter of about 1.3 inches. The length of syringe body 502 between first end 504 and second end 506 is about 6-7 inches. The inside of syringe body 502 is tapered so that second end 506 has an inside diameter greater than the inside diameter of interior portion 528 of the end wall 514. This taper is about 0.1° from horizontal for the majority of its length. The angle of tapering increases to about 1° at a point about 1 inch from the second end 506 of syringe 500. The interior portion 528 defining the cone-shaped surface 536 slopes at an angle of about 27° from vertical, and the vertex of the cone is rounded at a radius of about 0.25 inches. Each of ribs 532 is about 0.1 inches thick. The ribs 532 are spaced about 0.12 inches apart. The outlet port housing 526 has an outer diameter of about 0.3 inches, and an inner diameter of about 0.2 inches. The longitudinal axis of the outlet port housing 526 is parallel to and about 0.5 inches lower than the central longitudinal axis 508 of syringe body 502. The outlet port housing 526 is arranged relative to the syringe body 502, such that the outer diameter of the outlet port housing 526 intersects at a tangent point of the diameter of syringe body 502. The inlet port housing 520 has an outer diameter of about 0.4 inches and an inside diameter of about 0.2 inches. The longitudinal axis of the inlet port housing 520 is tilted about 10° from vertical toward the end wall 514. The inlet port 518 has a diameter of about 0.1 inches. The inlet port housing 520 is about 0.5 inches long measured from where the inlet housing 520 meets the syringe body 502 in the top portion 522 of the syringe 500.

ANOTHER EXEMPLARY SYRINGE HOLDER ARRANGEMENT

In reference now to FIGS. 18-20, a syringe holder arrangement is illustrated generally at 540 which may be used with syringe 500 depicted in FIGS. 12-17. It is noted that syringe holder arrangement 540 is compatible with angiographic injector system 10 illustrated in FIG. 1, wherein syringe holder arrangement 540 interfaces with main console 12, hand held remote control 14, tubing 42, peristaltic pump 44, saline check valve 46, waste check valve 48, saline bag 50, waste bag 52, and bag support rack 54. The operation of the injector system utilizing syringe holder arrangement 540 is essentially the same as the operations depicted and described in FIGS. 2A-2G, FIGS. 7A-7D, and FIGS. 8A-8C. Of course, some of the operations may differ due to the structural differences of the syringe holder arrangement (syringe holder 16, syringe body 18, syringe plunger 20, radiographic material reservoir 22, etc.) shown in FIG. 1 and the syringe holder arrangement 540 and syringe 500 shown in FIGS. 12 and 18.

In general, the syringe holder arrangement 540 includes a mounting chamber body 542, a door member 544, a rear plate 546, and a pressure containment sleeve 548. Preferred

assemblies further include a bottle holder assembly 550, an air column detector 552, and a manifold holder 554.

Mounting chamber body 542 is for holding syringe 500 in place during an angiographic operation. Mounting chamber body 542 is constructed and arranged to be durable enough to sustain large pressure loads from the fluid push through syringe 500. Mounting chamber body 542 has an arcuate configuration for receipt of sleeve 548. It includes a loading end 556 for receipt of syringe 500, and an actuating end 558 for receiving the actuator to reciprocate plunger 512 between its respective proximal and distal positions within syringe 500. The loading end 556 also corresponds to the front of mounting chamber body 542, and actuating end 558 corresponds to the back or rear of mounting chamber body 542.

Preferably, mounting chamber body 542 comprises a series of layers in order to provide a convenient and preferred structure for holding syringe 500. In particular, the outermost layer is an electroilluminescent layer. The electroilluminescent layer permits illumination of mounting chamber body 542 and the associated tubing. That is, the electroluminescent layer illuminates the fluid pathway of the contrast material as it is being conveyed from syringe 500 to downstream components and ultimately into the patient's cardiovascular system.

Adjacent to the electroilluminescent layer is a membrane heating element. This layer maintains heat of the contrast fluid in order to sustain a desired viscosity in the contrast fluid for conveying into the patient's cardiovascular system.

The next layer of mounting chamber body 542 and adjacent to the membrane heating element layer is a layer of foam. The foam layer keeps contact resistance with the syringe 500 high and thermal resistance low. It functions to take up tolerances and helps to snugly hold syringe 500 in place in syringe holder arrangement 540.

The last layer of mounting chamber body 542 is an aluminum extrusion. It provides for a rigid shape and for convenient manufacturing. A layer of adhesive attaches the foam layer to the aluminum extrusion.

As illustrated in FIG. 20, mounting chamber body 542 includes a pair of back flanges 559, 560 defining a groove 561 therebetween. Groove 561 provides for storage and containment of wires to syringe holder arrangement 540. A plate 562 slides in groove 561 and is securably attached thereto to provide for neat and convenient storage.

Still referring to FIG. 18, door member 544 is provided to allow for selective opening and closing of loading end 556 of body 542. That is, door member 544 is movable relative to

mounting chamber body 542 between positions allowing access to mounting chamber body 542, and into the interior of sleeve 548, and a position which blocks, or closes access to, the interior of sleeve 548. In the position where it closes access, door 544 provides for a stop surface to support and resist the load applied through the syringe 500 when the plunger is depressed.

In the particular embodiment illustrated, door member 544 is pivotable relative to mounting chamber body 542. This allows for quick and convenient loading and unloading of syringe 500 into holding arrangement 540. When door 544 is in its closed position, FIG. 19, it locks syringe 500 into place in holder arrangement 540.

In reference again to FIG. 18 and FIG. 20, door member 544 is a structure with a pair of flat, planar, opposite surfaces 563, 564. Preferably, it is a fabricated stainless steel plate with a thickness of about 0.4 - 1 inches. Flat surface 564, FIG. 20, is constructed and arranged for a sliding, abutting engagement with flat end wall 514 of syringe 500 and pressure sleeve 548. It also slides relative to and abuts against the end surface of sleeve 548. Because of the geometry of flat face 516 of end wall 514 of syringe 500, the thrust load exerted by the angiographic system 10 through syringe 500 can be managed by flat door member 544.

In reference again to FIG. 18, door member 544 defines a channel, groove, or slot 565. Slot 565 is an open, through-hole penetrating door member 544 and extending to the edge of door member 544. Slot 565 provides for slidable communication with outlet port housing 526 of syringe 500. That is, when syringe 500 is oriented properly for loading in holding arrangement 540, after syringe 500 is resting within sleeve 548, as door member 544 is pivoted to the closed position, FIG. 19, outlet port housing 526 slides within groove 565. Groove 565 permits outlet port housing 526 to extend and penetrate through door member 544 to permit liquid from syringe 500 to be conveyed to downstream components.

Still referring to FIG. 18, door member 544 includes a handle 566. Handle 566 extends from a side edge of door member 544 and allows for a user to conveniently pivot door member 544 between its closed position and its open positions. Door member 544 pivots about its lowest point preventing door member 544 from acting as a guillotine when acted upon by gravity. That is, the arrangement of door member 544 relative to its pivot point prevents injury to fingers.

In accordance with the invention, a door open sensor is provided. The door open sensor tells the user or operator if door member 544 is in an open position. That is, it functions as a safety feature such that angiographic system 10 will not be operated if door member 544 is not in a securely closed position. In the particular embodiment illustrated, the

door open sensor includes a magnet 567 in door member 544, and a Hall effect sensor in the mounting chamber body 542. When door member 544 is pivoted to its closed position, FIG. 19, magnet 567 is in contact with mounting chamber body 542. The Hall effect sensor senses the presence of magnet 567 and provides an indication to the operator that door member 544 is closed. When the Hall effect sensor does not sense the presence of magnet 567, it provides a signal to the operator that the door member 544 is not in the closed position, but in an open position. One suitable sensor is Hall effect sensor 55449A, available from Microswitch (a division of Honeywell).

Still referring to FIG. 18, pressure containment sleeve 548 is provided in the holding arrangement 540 to hold syringe 500 snugly between door member 544 and rear plate 546. Sleeve 548 helps to contain the pressure exerted through the syringe 500, and allows for large pressure forces through the syringe 500. The close fit between rear plate 546 and door member 544 holds the syringe 500 so that no forward/rearward movement is allowed.

In the particular embodiment illustrated, sleeve 548 is constructed and arranged to fit, or slide in the mounting chamber body 542. In the preferred embodiment, sleeve 548 is cylindrical, or tubular in shape with first and second open ends 568, 569 (FIG. 20). Sleeve 548 is preferably constructed from a strong, durable, basically transparent material in order to sustain large pressure loads and allow for visibility of the syringe therethrough. One preferred material includes polycarbonate.

In reference to FIG. 19, first end 568 of sleeve 548 is open and allows outlet port housing 526 to project, or extend therefrom and through slot 565 in door member 544. Second end 569, FIG. 20, permits an actuator from angiographic system 10 to penetrate sleeve 548 and access syringe plunger support member 617.

Referring again to FIGS. 18 and 19, it can be seen that door member 544 slides relative to first end 568 of sleeve 548, as door member 544 is moved between its closed position and open positions.

Sleeve 548 defines an open groove, or channel 570 extending from first end 568. Channel 570 accommodates a sensor 571. Sensor 571 is oriented relative to the valve assembly in inlet housing 520 in order to detect the state of the check valve. That is, sensor 571 detects whether the ball in the check valve is seated in its lowermost position or whether it has been moved out of its lowermost position. In the particular arrangement illustrated, sensor 571 is an emitter/detector interruptable infrared photodetector device. When the ball interrupts the infrared beam, a signal is sent indicating that the ball is seated in its lowermost position or seat. When the ball is moved out of its lowermost position or seat, the infrared

beam is not interrupted, and a signal is generated which indicates that the ball is out of its lower seat.

A connector 690 and wire 692 energize sensor 571. That is, connector 690 connects the electrical components and wires within groove 691 to sensor 571.

As can be seen in FIGS. 18 and 20, sensor 571 is generally U-shaped. The U-shape, in addition to enabling detecting of the ball in the check valve, also allows the inlet port housing 520 to be accommodated within sleeve 548 in holding arrangement 540. As illustrated in FIG. 19, when syringe 500 is loaded into holding arrangement 540, it is slid through sleeve 548, and sensor 571 permits inlet port housing 520 to rest within the U-shape of the sensor 571 and extend radially from sleeve 548. In this way, fluid communication is permitted from the source of contrast fluid and into syringe 500, even after syringe 500 is loaded within the holding arrangement 540. One type of sensor 571 useable is an infrared diode (part number SE-1450-004L) and photo-transistor pair (part number SD-1440-004L), both available from Microswitch (a division of Honeywell).

In the preferred embodiment, sleeve 548 is conveniently removable from mounting chamber body 542. In this manner, it may be cleaned and disinfected separate from chamber body 542. In the particular embodiment illustrated in FIG. 20, sleeve 548 is slidable relative to mounting chamber body 542 and can be lockably secured thereto through the cooperation of a locking pin 572 and a locking assembly 574 in the rear plate 546. Locking pin 572 extends from second end 569 of sleeve 548. Locking assembly 574 is a spring loaded locking member that engages and holds pin 572.

Again, in reference to FIG. 18, rear plate 546 is secured to mounting chamber body 542 and is in covering relation to second end 569 of sleeve 548. Rear plate 546 supports actuating end 558 of mounting chamber body 542.

In the particular embodiment illustrated, rear plate 546 has a rectangular configuration. Preferably, it is an aluminum fabricated plate, with a thickness of about 0.6 inches.

In reference now to FIG. 20, rear plate 546 defines an aperture 576 in a central portion therethrough. Aperture 576 allows access to the interior of sleeve 548. That is, aperture 576 permits the angiographic actuator to penetrate and move syringe plunger 512 between its respective proximal ends and distal ends of syringe 500.

In reference now to FIGS. 18 and 19, bottle holder assembly 550 is provided to hold a bottle 602 of contrast fluid in order to quickly and conveniently provide a constant source of contrast media to syringe 500 when it is loaded in holding assembly 540.

In the illustrated embodiment, bottle holder assembly 550 is secured to mounting chamber body 542. Bottle holder assembly 550 includes a column 578 and a neck portion 580.

Neck portion 580 is pivotable with respect to mounting chamber body 542 in the direction of arrow 581. The pivotable nature of neck portion 580 aids the ease of connecting the tubing from the bottle 602 of contrast media to inlet housing 520 of syringe 500.

Neck 580 includes universal detail 584 within grooves 586. Universal detail 584 is preferably a spring loaded configured member which allows bottle holder 550 to accommodate and hold bottles of various sizes.

In accordance with the present invention, an indicator arrangement is provided to provide information whether a bottle is in bottle holder assembly 550. In the preferred embodiment, a switch is provided in universal detail 584. When a bottle 602 of contrast is within neck 580, bottle 602 presses against the spring in universal detail 584, which actuates the switch. When the switch is actuated, it provides a visual signal to the system operator that a bottle is in fact in the bottle holder assembly 550. If the switch is not actuated, a signal is provided to the user that there is no bottle in holder assembly 550. One suitable switch is a microswitch MMGGDILOO, available from C&K.

In accordance with the present invention, a sensor is provided to indicate if the fluid level in bottle 602 of contrast is either below a certain level or empty. Preferably, the sensor includes a sensor provided within groove 586 in neck 580. The sensor detects when the fluid level in the bottle 602 has dropped below the level of the sensor in neck 580. Preferably, the sensor is a reflective, infrared device. One type of sensor useable is infrared sensor H0A1405-2, available from Microswitch (a division of Honeywell).

In reference again to FIGS. 18 and 19, air column detector 552 is provided to detect the presence of air in fluid line 588 (FIG. 19). Air column detector 552 is analogous to air bubble detector 172, described above. It uses ultrasonic means to detect the presence of air in line 588. One suitable ultrasonic means is available from Introtek of New York.

Air column detector 552 defines a groove 590, FIG. 18, which provides a friction fit with fluid line 588. That is, the tubing snaps into groove 590 where it is securely held therein. Holders 627, 628 swing down over fluid line 588 to secure it in place (FIG. 19). A flange 592 provides for attachment of the air column detector 552 to mounting chamber body 552.

In reference now to FIG. 22, air column detector 552 is shown engaging fluid line 588 which has been wrapped around itself to form a loop 651. Although no particular theory with respect to this arrangement is asserted hereto, it is believed that by forming a loop 651 in fluid

line 588, any air bubbles present within fluid line 588 will be at a top side of the tube due to buoyancy resulting from gravitational forces and centrifugal forces due to the fluid flow. Gravitational forces push the bubble to the top side of tube 588. Centrifugal forces push the bubble to the inside of the bend radius of loop 651. By the section being at the bottom quadrant, both of these forces will be in the same direction pushing the bubble to the inside of the bend of the loop 651 and the top of tube 588, independent of bend radius or fluid velocity. Thus, the bubble is forced to the top side of tube 588. In certain arrangements, this tends to enhance the detection of any air bubbles by air column detector 552.

Again in reference to FIGS. 18 and 19, manifold holder 554 is provided to secure and hold a manifold, analogous to manifold 26, described above. A clamp structure 597 holds the manifold securely in place. Manifold holder 554 is mounted on a flange 594, which is secured to mounting chamber body 542. Manifold holder 554 is mounted on flange 594 in a slot 596, FIG. 20, to permit manifold holder 554 to slide back and forth within groove 596. This permits manifold holder 554 to accommodate different lengths of tubing 598, FIG. 19, from outlet port housing 526 of syringe 500.

Manifold holder 554 is configured and shaped to permit the manifold to snap in only one orientation. In this way, it can be assured that the manifold is always oriented in the same position relative to manifold holder 554. Because of this, a sensor 599 can detect the position of the valve within the manifold. Sensor 599 is positioned in an integral part with manifold 554. Sensor 599 preferably is an inductive type device. One type of sensor useable in the embodiment shown is an inductive sensor (part number IFRM 12P1701\L) available from Baumer.

Attention is again directed to FIG. 20. In FIG. 20, a pair of volume indicators 606, 607 are illustrated. Volume indicators 606, 607 are oriented relative to mounting chamber body 542, such that when syringe 500 is situated within mounting chamber body 542, volume indicators 606, 607 provide a visual cue and indication for the level of fluid within syringe body 502. As shown in FIG. 20, volume indicators 606, 607 each include a plurality of marks 608. As the fluid level within syringe body 502 changes, the user is able to visually detect where the level is by comparing it against the marks 608.

In accordance with the present invention, a method for mounting or loading a syringe is provided. The method includes a step of positioning a syringe through a front aperture in a syringe holder arrangement. This includes sliding a syringe, such as syringe 500 in through the front end of a syringe holder arrangement 540. Using the components illustrated in the drawings, syringe 500 is oriented to line up with the open end of the first end of sleeve 548.

That is, second end 506 of syringe 500 is aligned with the front of sleeve 548, and the inlet port housing 570 is aligned with slot 570. The rear, or second end 506, of syringe 500 (that is, the plunger receiving end) is first slid through the open end defined by first end 568 of sleeve 548. This is followed by the fluid-dispersement end of the sleeve, i.e., first end 504 defining flat face 516. Syringe 500 is slid into the interior of sleeve 548.

Next, the door is closed. This blocks further access to the interior of sleeve 548. This also provides for a stop surface, engagement surface, or abutting surface for syringe 500 in order to absorb and sustain pressure load through syringe 500. Specifically, door member 564 is pivoted from one of its open positions, FIG. 18, to its closed position, FIG. 19. The user grasps handle 566 and pivots the door to close the opening. As door member 544 is being pivoted, flat surface 564 of the door is slid relative to flat face 516 of syringe 500, and relative to first end portion 568 of sleeve 548. As door member 544 is moved into its closed position, outlet tube housing 526 communicates with and slides through groove 565.

To unload syringe 500 from syringe holder arrangement 540, the above process is basically done in reverse. Door member 544 is pivoted from its closed position, FIG. 19, into one of its open positions, such as that illustrated in FIG. 18. Syringe 500 is then removed from holder assembly 540. Specifically, syringe 500 is slid from the interior of sleeve 548. The front end of syringe 500, that is, the end with flat face 516, is slid out first, followed by the rear end, or second end 506.

In accordance with the present invention, the angiographic system described herein is constructed and arranged to ensure that syringe 500 is not re-used. That is, the angiographic system of the present invention includes features to ensure that syringe 500 is disposed of after use with one patient and not accidentally re-used on a new, different patient. As embodied herein, syringe 500 includes structure on its plunger support member 617 to ensure single use. As illustrated in FIG. 21, plunger support member 617 defines a plurality of projections or tabs 610. Tabs 610 project or extend radially inwardly toward the center or apex of plunger 512. Tabs 610 are constructed of a flexible, deformable material, but also frangible or breakable, such that when the actuator engages plunger support member 617, tabs 610 are bent inwardly to accommodate the actuator. However, when syringe 500 is removed from the actuator, tabs 610 are broken, and plunger support member 617 is destroyed. This prevents syringe 500 from being re-used.

After a period of use, it may be desirable to remove pressure containment sleeve 548 for cleaning. To do this, rear plate 546 is shifted to disengage and release locking pin 572. While locking pin 572 is disengaged from locking assembly 574, sleeve 548 may be grasped

at a first end 568 and slid out from its snug engagement with mounting chamber body 542. At this point, sleeve 548 may be cleaned.

To reinsert the sleeve 548, sleeve 548 is slid back into secure, snug engagement with the mounting chamber 542. Locking assembly 574 is shifted to permit locking engagement with locking pin 572.

EXEMPLARY SYRINGE PLUNGER ARRANGEMENTS

Referring back to FIG. 13, syringe plunger is usable in the angiographic systems described above. As discussed previously, plunger 512 includes plunger support member 617 and cover 618. Preferably, cover 618 is injection-fluid-compatible (that is, chemically compatible and biochemically compatible with the injection fluid). Any contact with the injection fluid is preferably made with cover 618 and, therefore, plunger support member 917 need not be fabricated from a long-term chemically and biochemically compatible material. Plunger support member 617 may be fabricated from a relatively rigid and strong polymer such as ABS, styrene, acetal, nylon, polycarbonate, and the like or from a metal such as stainless steel, aluminum, and the like. When plunger support member 617 is fabricated from a metal, a coating may be provided to prevent the injection fluid from reacting with plunger support member 617. Cover 618 may comprise, for example, an elastomeric material such as a thermoplastic elastomer, synthetic materials, or rubber.. Such elastomeric materials for cover 618 generally have hardness in the range of approximately 50-60 Shore A, low compression set characteristic at elevated temperatures, high chemical resistance and isotropic characteristics, no plasticizers, and low levels of organic and metallic extractables.

Referring back to FIG. 13, exemplary cover 618 includes a forward portion having a cone-shaped surface. A side portion of cover 618 forms a cylindrical sealing engagement with the inner sidewall of pumping chamber 510 and includes a plurality of circumferential seal ribs 619 which protrude from the outer perimeter of the cover 618 to more effectively create a seal between cover 618 and the inner sidewall of syringe body 502 for containment of the injection fluid.

Referring to FIGS. 23 and 24A-24C, an actuator 700 cooperates with plunger 512 to impart reciprocal motion thereto. Actuator 700 comprises a drive piston 702 and an actuator head 704. A distal end of the drive piston 702 is connected to actuator head 704 while a proximal end of drive piston 702 is coupled to the motors housed within console 12. Actuator head 704 includes a circumferential flange 706.

As best illustrated in FIGS. 24A-24C, plunger support member 617 has a main body 708 which is cone-shaped so that the proximal diameter is greater than the distal diameter.

The reduction in diameter allows the distal portion of main body 708 to pass through aperture 576 of rear plate 546. Plunger support member 617 includes three capture members 710 cantileverly protruding in a proximal direction from main body 708, and capture members 710 include latches 712 which capture and retain flange 706 of actuator head 704. Capture members 710 are configured to flex radially outwardly when contacted by flange 706 and subsequently "snap back" to capture flange 706. As actuator head 704 moves forward to contact plunger 512, beveled surfaces 714 engage flange 706 and are forced radially outwardly until flange 706 passes beyond and over inner shoulders 716 of latches 712. This design enables actuator head 704 to engage plunger 512 easily at any axial position within syringe body 502. For the present embodiment, approximately 7-10 lbs of axial force is required for engagement, which is less than the initial stiction force of cover 618 such that plunger 512 remains stationary relative to syringe body 502 during the engagement procedure. If the initial stiction force is inadequate, outlet port 524 and inlet port 520 of syringe 500 may be occluded. The actuator may be extended rapidly to increase pressure within the syringe body 502. As the pressure increases, further forward movement of plunger 512 is restricted and the actuator engages with plunger 512 at a force lower than "cracking" pressure of the occlusions (e.g. 60 psi).

After retention of actuator head 704 by capture members 710, plunger 512 remains engaged with actuator 700 at relatively high rearwardly directed forces (up to approximately 100 lbs), while plunger 512 is capable transmitting forward thrusts greater than 1500 lbs to the syringe contents during an injection.

Referring back to FIGS. 24A-24C, fingers 718 extend radially outwardly from an outer surface of capture members 710. Ends of fingers 718 extend outwardly at a distance approximately equivalent to an outer circumference of plunger support member 617. During the disengagement procedure, actuator 700 is retracted and the distal portion of main body 708 passes through aperture 576 of rear plate 546. Rearward movement of plunger 512 substantially terminates when fingers 718 abut against an inner surface 720 of rear plate 546 (see FIG. 18), wherein capture members 710 flex radially outwardly and disengage with flange 706 of actuator head 704. In the exemplary embodiment, capture members 710 are designed to permanently deform during disengagement to ensure that syringe 500 is disposed of after use with one patient and not accidentally re-used on a new, different patient. By providing capture members 710 which are deformable instead of frangible or breakable, problems encountered with particulates remaining and causing problems during subsequent interconnections are avoided. Thus, plunger 512 may be connected and disconnected with

actuator 700 within syringe body 502 or at a remote location without the need for outside toggling or actuation. Furthermore, connection may be made at any location within syringe 500 and any time, but disconnection may be performed at only one predetermined location (plunger 512 at its fully retracted position). Of course, the capture members may be configured to break away if desired to prevent re-use of the syringe. For example, capture members may be formed of a relatively rigid material which will break away from the main body when the fingers abut against the inner surface of the rear plate. In an alternate embodiment of the present invention, the advancement of the actuator 700 may be used to couple the plunger 512 to the actuator head 704. For example, the actuator 700 may be advanced such that the actuator head 704 engages the plunger 512. Thereafter, the plunger 512 and actuator head 704 are advanced through the syringe body 502 and forcibly engages the forward plate of the main body, thereby seating the plunger 512 on the actuator head 704.

FIG. 25 illustrates another embodiment of a syringe plunger arrangement in accordance with the present invention. Plunger 750 includes cover 618 and a plunger support member 752. Plunger support member 752 is magnetically attached to an actuator 754. Plunger support member 752 includes a first insert 756 comprising a ferrous metal, permanent magnet, or electromagnet, while actuator 754 includes a second insert 758 comprising a ferrous metal, permanent magnet, or electromagnet. Any combination of a ferrous metal, permanent magnet, and electromagnet may be used when configuring first 756 and second insert 758 as long as a permanent magnet or an electromagnet is included in one of the inserts 756, 758. For example, the syringe plunger arrangement may be configured so that first 756 includes a ferrous metal and second insert 758 includes an electromagnet, or first insert 756 includes a ferrous metal and second insert 758 includes a permanent magnet, or first insert 756 includes a permanent magnet and second insert 758 includes a permanent magnet, or first insert 756 includes a permanent magnet and second insert 758 includes an electromagnet, etc.

Referring back to FIG. 25, plunger support member 752 includes a base 760 having an outer diameter larger than aperture 576 of rear plate 546 (see FIG. 18). As actuator 754 is retracted through aperture 576, plunger 750 is driven rearwardly until base 760 abuts against inner surface 720 of rear plate 546. Upon further retraction of actuator 754, plunger 750 is disengaged from actuator 754. Some of the advantages of utilizing a magnetic syringe plunger arrangement is that a "zero" engagement force is required to engage plunger 750 with actuator, a desired disengagement force can be easily obtained by selecting appropriate inserts 756, 758, reconnection and re-use of syringe 500 can be easily performed because plunger

support member 752 is not damaged during the disconnection procedure, and particulates from frangible or breakable parts are not present to cause problems during reconnection.

It should be noted that construction of the syringe plunger arrangement shown in FIG. 25 is not limited to the above description. For example, the plunger support member may include deformable fingers similar to the embodiment described in FIGS. 24A-24C to prevent re-use of syringe 500. Furthermore, at least one of the first and second insert may be provided with a switchable electromagnet such that the plunger may be disengaged from the actuator at any position relative to the syringe body with a substantially "zero" disengagement force.

FIG. 26 illustrates another embodiment of a syringe plunger arrangement in accordance with the present invention. A plunger 800 includes a plunger support member 802 and cover 618, wherein plunger support member 802 is removably connected to an actuator 804. A main body 806 of plunger support 802 includes a circumferential groove 808. A first capture member 810 is pivotally coupled to a distal portion of actuator 804, and an opposing second capture member 812 is pivotally coupled to the distal portion of actuator 804. Distal ends of first 810 and second capture member 812 include a latch 814 projecting outwardly from an inner surface thereof, and proximal ends of first 810 and second capture member 812 include a ramped lug 816 projecting outwardly from an outer surface thereof. The distal ends of capture members 810, 812 are biased in a radially outward direction by a spring 818.

As actuator 804 moves forward to contact plunger 800, beveled surfaces 820 engage main body 806 of plunger support member 802 and are forced radially outwardly until latches 814 engage circumferential groove 808 and move radially inwardly. After retention of actuator 804 by capture members 810, 812, plunger 800 remains engaged with actuator 804. The syringe plunger arrangement exhibits a relatively low attachment force (less than 20 lbs) and relatively high retention force (greater than 100 lbs).

During the disengagement procedure, actuator 804 is retracted and the distal portion passes through aperture 576, ramped lugs 816 slidingly engage with sidewall 822 of aperture 576, capture members 810, 812 pivot such that the proximal ends are driven radially inwardly and the distal ends are driven radially outwardly, and latches 814 disengage from circumferential groove 808.

FIGS. 27A-27G illustrate another embodiment of a syringe plunger arrangement in accordance with the present invention. More specifically, the present embodiment is particularly useful with injection systems capable of being radially loaded, such as the system disclosed in the applicant's co-pending U.S. Patent Application Serial No. 09/577,906 filed on

May 24, 2000 entitled "A Pressure Sleeve Assembly". Those skilled in the art, however, will appreciate the present embodiment may be used with a plurality of radially loaded injection systems. FIGS. 27A-27B show a pressure sleeve assembly 830, which includes a longitudinal base member 832 having a receptacle area 834, a cylinder 836 for housing a syringe (not shown), a pivotal arm structure 838, a rear plate 840, and a forward plate 842. The cylinder 836, which is capable of receiving an injection syringe (not shown), is mounted on the pivotal or "hinged" arm structure 838, which, in turn, is movable between an open position, as shown in FIG. 27A, where the cylinder 836 is disposed away from the receptacle area 834, and a closed position, as shown in FIG. 27B, where the cylinder 836 is disposed within the receptacle area 834. The rear plate 840 disposes an actuator orifice 844, which the actuator 854 traverses during linear movement. The front plate 842 includes a curved slot 846, which receives and guides a fluid exit port 848 formed on the syringe (not shown) as the cylinder 836 is rotated into the closed position. The actuator 854 further comprises a circumferential groove 856, as shown in FIG. 27F, which protrudes slightly into the receptacle area 834 of the pressure sleeve assembly 830. The portion of the cylinder 836 located proximal to the rear plate 840 disposes a plunger engagement slot 850, which prevents the protruding actuator 854 from impeding the rotation of the cylinder 836.

FIGS. 27C-27G show the plunger 850 of the present embodiment in greater detail. As shown in FIGS. 27C-27E, the plunger 850 includes a plunger support member 852 defining a U-shaped tongue 858, and a cover 618 positionable on the plunger support member 852. As shown in FIG. 27F, the rotation of the cylinder 836 from an open position to a closed position causes the U-shaped tongue 858 to slidably engage the circumferential groove 856 formed on the actuator 854, thereby resulting in the coupling of the plunger 850 to the actuator 854. Conversely, movement of the cylinder 836 from a closed position to an open position causes the U-shaped tongue 858 formed on the plunger 850 to slidably disengage the circumferential groove 856 formed on the actuator 854, thereby resulting in the detachment of the plunger 850 to the actuator 854. FIG. 27G shows the circumferential groove 856 formed on the actuator 854 protruding from the actuator orifice 844 formed in the rear plate 840, thereby permitting the plunger 850 to be slidably coupled to the actuator 854.

In an alternate embodiment, the plunger 850 may be manually connected to actuator 854 by sliding a U-shaped tongue 858 of plunger support member 852 onto circumferential groove 856, wherein U-shaped tongue 858 remains engaged with circumferential groove 856 when plunger 850 is reciprocated within syringe body 502. Plunger 850 is disconnected from

actuator 854 by manually sliding U-shaped tongue 858 away from circumferential groove 856.

FIG. 28 illustrates another embodiment of a syringe plunger arrangement in accordance with the present invention. A plunger 900 includes a plunger support member 902 and cover 618. Plunger support member 902 includes a proximal base 904 defining an aperture 906. A first capture member 908 and a second capture member 910 are pivotally coupled to a distal portion of an actuator 912 at a common point 914. Distal ends of first 908 and second capture member 910 each include a ramped lug 916 extending outwardly from an outer surface thereof, and proximal ends of first 908 and second capture members 910 each include a latch 918 extending outwardly from an inner surface thereof. The distal ends of capture members 908, 910 are biased in a radially outward direction by a spring 920.

As actuator 912 moves forward to contact plunger 900, beveled surfaces 922 engage aperture 906 of plunger support member 902 and are forced radially inwardly until latches 918 engage an inner surface 924 of base 904. After retention of actuator 912 by capture members 908, 910, plunger 900 remains engaged with actuator 912. The syringe plunger arrangement exhibits a relatively low attachment force (less than 20 lbs) and relatively high retention force (greater than 100 lbs). During the disengagement procedure, actuator 912 is retracted and the distal portion passes through aperture 576, ramped lugs 916 slidingly engage with sidewall 822 of aperture 576, capture members 908, 910 pivot such that both the proximal and distal ends are driven radially inwardly, and latches 918 disengage from inner surface 924 of base 904.

FIG. 29 illustrates another embodiment of a syringe plunger arrangement in accordance with the present invention. A plunger 950 includes a plunger support member 952 and a cover 618. A retaining ring 954 is disposed at the proximal end of the syringe body 502. Retaining ring 954 is configured to remain fixedly attached to syringe body 502, wherein flange 956 abuts against the proximal end of syringe body 502. Plunger 950 is releasably connected to retaining ring 954 by ribs 958. Plunger 950 further includes capture/engaging members which engage with the actuator. These capture/engaging members may be configured similarly to the embodiments described above. Plunger 950 and retaining ring 954 are configured such that the retaining force of the ribs 958 is greater than the engagement force of the capture members. As actuator 960 is extended and contacts plunger 950, plunger 950 remains stationary within syringe body 502 by retaining ring 954. After plunger 950 engages with the actuator, retaining ring 954 releases plunger 950, and plunger 950 is allowed to be driven forward and rearward.

FIG. 30 illustrates a still further embodiment of a syringe plunger arrangement in accordance with the present invention. A plunger 1000 includes a plunger support member 1002 and cover 618. Plunger support member 1002 includes a "Christmas tree" type fastener 1004. Fastener 1004 includes a plurality of tongue members 1006 extending radially outward. An actuator 1008 moves forward to contact plunger 1000. An aperture 1010 is defined within a distal end of actuator 1008. When actuator 1008 is extended to contact plunger 1000, fastener 1004 engages with aperture 1010. Tongue members 1006 are angled so that the engagement force is less than the retaining force.

FIGS. 31A-31M illustrate yet another embodiment of a syringe plunger arrangement capable of detachably mounting to an actuator 1034 in accordance with the present invention. FIG. 31A shows the plunger 1020 of the present embodiment, which includes a plunger support member 1022 and a cover 1024. As shown in FIG. 31B, the plunger support member 1022 comprises a receiving aperture 1026 formed by a base portion 1028. As shown in FIGS. 31C and 31D, the at least one retaining member 1030 is positioned on said base portion 1028 and projects inwardly to the receiving aperture 1026. The at least one retaining member 1030 is capable of capturing and retaining a flange 1032 formed on the actuator head 1038. The at least one retaining member 1030 is configured to flex outwardly when contacted by an engagement member 1062A and 1062B, and subsequently "snap back" to capture flange 1032. As actuator 1034 moves forward to contact plunger 1020, the at least one retaining member 1030 is forced outwardly by the engagement members 1062A and 1062B until the flange 1032 is engaged by the at least one retaining member 1030. The at least one retaining member 1030 may be beveled or angled to effectuate the coupling of the plunger 1020 to the actuator 1034. This design enables actuator 1034 to engage plunger 1020 easily at any axial position within syringe body (not shown).

FIGS. 31E-31G show various views of the actuator 1034 in accordance with the present invention. As shown in FIG. 31E, the actuator 1034 comprises an actuator body 1036 connected to actuator head 1038. The actuator head 1038 comprises an alignment shaft 1040 co-axially aligned along the longitudinal axis of the actuator body 1034, which is positioned between a first collet member 1042 and a second collet member 1044. An alignment device 1046 may be attached to or integrally formed on the alignment shaft 1040.

As shown in FIGS. 31F-31G, the first collet member 1042 comprises a planar surface 1048 and an arcuate second surface 1060. The planar surface 1048 further comprises an alignment shaft receiving channel 1050a and further disposes a pair of biasing lumens, 1052a and 1052b, respectively. An alignment pin orifice 1054a may be formed within the alignment

shaft receiving channel 1050a of the first collet member 1042. The arcuate second surface 1060a comprises an engagement member 1062a, a flange portion 1064a, and a detachment member 1066a.

The second collet member 1044 is substantially identical to the first collet member 1042, in that the second collet member 1044 comprises a planar surface 1068 and an arcuate second surface 1070. The planar surface 1068 further comprises an alignment shaft receiving channel 1050b and further disposes a pair of biasing lumens, 1072a and 1072b, respectively. An alignment pin orifice 1054b may be formed within the alignment shaft receiving channel 1050b of the second collet member 1044. The arcuate second surface 1060b forms or positions an engagement member 1062b, a flange portion 1064b, and a detachment member 1066b.

FIGS. 31H-31I show various views of the actuator 1034 in accordance with the present invention. FIG. 31H shows a bottom view of the actuator head 1034. Likewise, FIG. 31I shows a top view of the actuator head 1034. As shown in FIGS. 31H-31I, biasing members 1076a and 1076b are used to slidably couple the first and second collet members 1042 and 1044, respectively. In addition, the biasing members 1076a and 1076b bias the first and second collet members 1042 and 1044 outwardly. As a result of the outward force applied by the biasing members 1076a and 1076b, the flange 1032, which is formed by flange portions 1064a and 1064b, is capable of forming at least a first diameter D when no constrictive force is applied to the actuator head 1038, and at least a second smaller diameter D' when a constrictive force is applied to the first and second collet members 1042 and 1044.

An alignment pin 1078 may be used to retain the alignment shaft 1040 within the actuator head 1038 and to slidably couple and align the actuator head 1038. The alignment pin 1078 is positioned within an alignment pin orifice 1080 formed in the alignment shaft 1040, and is in communication with the alignment pin orifices 1052a and 1052b formed on the first and second collet members 1042 and 1044.

The alignment device 1046, which may be attached to or integrally formed on the alignment shaft 1040, assures the first and second collet portions 1042 and 1044 are equidistant from the alignment shaft 1040. In addition, the alignment device 1046 may be used to define a minimum smaller diameter D' of the flange 1032.

FIGS. 31J-31K show the process of the plunger 1020 being coupled to the actuator head 1038. As shown in FIG. 31J, the actuator head 1038 is coaxially aligned with the receiving aperture 1026 formed on the base portion 1028 of the plunger support member 1022. Thereafter, the actuator 1034 is advanced, thereby causing the engagement members

1062a and 1062b formed on the actuator head 1038 to engage the at least one retaining member 1030 positioned on base portion 1028 of the plunger support member 1022. In response, the at least one retaining 1030 flexes outwardly while radially applying a constrictive force to the actuator head 1038. This application of constrictive force results in the first and second collet members 1042 and 1044 sliding inwardly and decreasing diameter of the flange 1032 to diameter D'.

As the movement of the actuator 1034 continues, the engagement members 1062a and 1062b advance into the receiving aperture 1026 formed on the base portion 1028 of the plunger support member 1022. Thereafter, the at least one retaining member 1030 engages the flange 1032. As shown in FIG. 31K, the biasing members 1076a and 1076b cause the first and second collet portions 1042 and 1044 to slide outwardly and effectuate an increase in the diameter of the flange 1032 from diameter D'. At this point, the plunger 1020 is coupled to the actuator 1034.

FIGS. 31L-31M show the process of the plunger 1020 being detached to the actuator head 1038. Following the injection of material, the plunger 1020 and actuator 1034 are retracted. During retraction, the actuator 1034 approaches the aperture 576 (see FIG. 18) formed on the rear plate 546 of the syringe holder arrangement 540. The diameter of the aperture 576 is slightly smaller than the diameter of the actuator head 1038, thereby causing the detachment members 1066a and 1066b formed on the first and second collet members 1042 and 1044 engage the rear plate 546 of the syringe holder arrangement 540. The retraction of the actuator and the angled wall forming the detachment members 1066a and 1066b cooperatively apply a constrictive force to the actuator head 1038, resulting in the first and second collet members sliding inwardly and decreasing diameter of the flange 1032 to diameter D'. Thereafter, the at least one retaining member 1030 disengages the flange 1032 and the actuator 1034 detaches from the plunger 1020.

Additional embodiments of a syringe plunger arrangement can be found on Exhibit A, and further operation of the embodiments illustrated in Figures 1 and 18 can be found on Exhibit B, attached hereto and specifically made a part thereof.

Having thus described exemplary embodiments of the present invention, it is noted that the disclosure herein are exemplary only and that various other alterations, adaptations and modifications may be made within the scope of the present invention. Accordingly, the present invention is not limited to the specific embodiments as illustrated herein. For example, the various syringe plunger arrangements may be configured with additional or fewer capture members. For example, the actuator described in FIGS. 26 may comprise an

additional two capture members such that four capture members are provided to secure the syringe plunger with the actuator.

We claim:

1. A plunger for use in a syringe, the plunger comprising:

a releasable connection mechanism adapted to make a releasable connection with an actuating shaft of the syringe, the actuating shaft adapted for reciprocal motion to control movement of the plunger;

wherein the releasable connection mechanism includes a capture member projecting proximally from the plunger, the capture member adapted to flex radially outwardly when contacted by the actuating shaft to form a releasable engagement with the actuating shaft when the actuating shaft and the capture member are in an engagement position relative to each other, the capture member further adapted to release the actuating shaft upon engagement with a releasing member of the syringe.

2. The plunger of claim 1, wherein the release member is a plate defining an aperture, wherein the actuating shaft passes through the aperture.

3. The plunger of claim 2, further comprising a finger extending radially outwardly from the capture member, the finger adapted to abut against an inner surface of the plate to disengage the capture member from the actuating shaft.

4. A syringe for use with an injector having an actuating shaft, the syringe comprising:

a syringe plunger having a releasable connection mechanism adapted to releasably connect with the actuating shaft, the connection mechanism including a capture member projecting proximally from the syringe plunger;

wherein the capture member is adapted to flex radially outwardly when contacted by the actuating shaft to form a releasable engagement with the actuating shaft when the actuating shaft and the capture member are in an engagement position; and

wherein the capture member is adapted to release the actuating shaft upon engagement with a release member of the syringe.

5. The syringe of claim 4, wherein the release member is a plate defining an aperture, wherein the actuating shaft passes through the aperture.

6. The syringe of claim 5, further comprising a finger extending radially outwardly from the capture member, the finger adapted to abut against an inner surface of the plate to disengage the capture member from the actuating shaft.

7. An injection system comprising:

a syringe body having a distal portion and a proximal portion, the syringe body defining a pumping chamber;

a syringe plunger located in the pumping chamber and adapted for reciprocal motion, the syringe plunger having a capture member projecting outwardly in a proximal direction;

an actuating shaft coupled to the syringe plunger and movable through the syringe body to control movement of the syringe plunger;

wherein the capture member is adapted to flex radially outwardly when contacted by the actuating shaft to form a releasable engagement with the actuating shaft when the actuating shaft and the capture member are in an engagement position; and

a release actuator disposed proximal to the syringe body;

wherein the capture member is adapted to release the actuating shaft upon engagement with the release actuator.

8. The injection system of claim 7, wherein the release actuator is a plate defining an aperture for allowing manipulation of the syringe plunger, wherein the capture member is adapted to flex radially outwardly when contacting a distal surface of the plate such that the syringe plunger disengages with the actuating shaft.

9. The syringe of claim 8, further comprising:

a groove circumscribing the actuator shaft;

a latch disposed on an inner surface of the capture member, the latch secured to the groove when the actuating shaft and the capture member are in the engagement position;

a finger extending radially outwardly from the capture member, the finger adapted to abut against an inner surface of the plate to disengage the capture member from the actuating shaft.

10. The syringe of claim 9, wherein the syringe plunger is cylindrically shaped and has a first outer diameter, wherein the actuating shaft is cylindrically shaped and has a second outer diameter, wherein the first outer diameter is greater than the second outer diameter,

wherein an outer end of the finger extends substantially beyond the second outer diameter and extends substantially within the first outer diameter such that actuating shaft is adapted to pass through the aperture of the plate and the finger is restricted from passing through the aperture of the plate.

11. A method of connecting and disconnecting a syringe plunger from an actuating shaft of an injection system, comprising:

providing a syringe body having a distal portion and a proximal portion, the syringe body defining a pumping chamber;

providing a syringe plunger within the pumping chamber, the syringe plunger having capture member projecting outwardly therefrom in a proximal direction;

driving the actuating shaft towards the syringe plunger such that a distal portion of the actuating shaft forces the capture member radially outwardly to form a releasable engagement with the syringe plunger; and

retracting the actuating shaft such that the capture member abuts against a release member and forces the capture member radially outwardly to disengage the syringe plunger from the actuating shaft.

12. The method of claim 11, further comprising passing the actuating shaft through an aperture of the release member, the release member being a plate located proximal to the syringe body.

13. The method of claim 11, wherein said providing a syringe plunger further includes providing a finger which extends radially outwardly from the capture member such that the finger abuts against an inner surface of the plate and causes the capture member to flex radially outwardly.

14. An injection system comprising:

a syringe body having a distal portion and a proximal portion, the syringe body defining a pumping chamber;

a syringe plunger located in the pumping chamber and adapted for reciprocal motion within the pumping chamber;

an actuating shaft coupled to the syringe plunger and movable through the syringe body to control movement of the plunger, the actuating shaft having a pivot member disposed

at a distal portion thereof;

a release actuator disposed proximal to the syringe body;

wherein a distal portion of the pivot member is adapted to project radially outwardly when contacted by the syringe plunger to form a releasable engagement with the syringe plunger when the actuating shaft and the pivot member are in an engagement position; and

wherein the distal portion of the pivot member is adapted to release the actuating shaft upon engagement of a proximal portion of the pivot member with the release actuator.

15. The injection system of claim 14, further comprising:

a groove circumscribing a surface of the syringe plunger;

wherein the release actuator is a plate defining an aperture for allowing manipulation of the syringe plunger;

wherein the distal portion of the pivot member includes a latch projecting outwardly from an inner surface thereof, the latch secured to the groove when the actuating shaft and the pivot member are in the engagement position; and

wherein the proximal portion of the pivot member includes a ramped lug projecting outwardly from an outer surface thereof, the ramped lug slidingly engaging with a sidewall of the aperture to drive the proximal end of the pivot member radially inwardly and to drive the distal end of the pivot member radially outwardly such that actuating shaft disengages with the syringe plunger.

16. The injection system of claim 15, wherein the pivot member includes a first pivot member opposing a second pivot member, the injection system further comprising:

a bias member coupled to the first pivot member and the second pivot member, the bias member forcing the proximal ends of the first pivot member and the second pivot member in a radially outward direction, and the bias member forcing the distal ends of the first pivot member and the member in a radially inward direction.

17. The injection system of claim 16, wherein the bias member is a spring.

18. A method of connecting and disconnecting a syringe plunger from an actuating shaft of an injection system, comprising:

providing a syringe body having a distal portion and a proximal portion, the syringe body defining a pumping chamber;

providing an actuating shaft capable of coupling with the syringe plunger, the actuating shaft having a pivot member disposed at a distal portion thereof; and

providing a release actuator proximal to the pumping chamber;

wherein a distal portion of the pivot member projects radially outwardly when contacted by the syringe plunger to form a releasable engagement with the syringe plunger when the actuating shaft and the pivot member are in an engagement position; and

wherein the distal portion of the pivot member releases the actuating shaft upon engagement of a proximal portion of the pivot member with the release actuator.

19. The method of claim 18, further comprising:

providing a groove circumscribing a surface of the syringe plunger;

wherein the release actuator is a plate defining an aperture for allowing manipulation of the syringe plunger;

wherein the distal portion of the pivot member includes a latch projecting outwardly from an inner surface thereof, the latch secured to the groove when the actuating shaft and the pivot member are in the engagement position; and

wherein the proximal portion of the pivot member includes a ramped lug projecting outwardly from an outer surface thereof, the ramped lug slidingly engaging with a sidewall of the aperture to drive the proximal end of the pivot member radially inwardly and to drive the distal end of the pivot member radially outwardly such that actuating shaft disengages with the syringe plunger.

20. The method of claim 19, wherein the pivot member includes a first pivot member opposing a second pivot member, the injection system further comprising:

coupling a bias member to the first pivot member and the second pivot member, the bias member forcing the proximal ends of the first pivot member and the second pivot member in a radially outward direction, and the bias member forcing the distal ends of the first pivot member and the second member in a radially inward direction.

21. A plunger for use in a syringe having an actuating shaft adapted for reciprocating motion to control movement of the plunger, the plunger comprising:

a U-shaped tongue disposed at a proximal portion of the plunger, the U-shaped tongue releasably connected with a circumscribing groove of the actuating shaft;

wherein the plunger is in an engaged position with the actuating shaft when the U-

shaped tongue is slidingly fitted onto the circumscribing groove; and

wherein the plunger is in a disengaged position with the actuating shaft when the U-shaped tongue is slidingly withdrawn from the circumscribing groove.

22. An injection system comprising:

a syringe body having a distal portion and a proximal portion, the syringe body defining a pumping chamber;

a syringe plunger located in the pumping chamber and adapted for reciprocal motion between a position proximate to the proximal portion and the distal portion, the syringe plunger having first aperture disposed at a proximal portion thereof; and

an actuating shaft coupled to the plunger and movable through the syringe body to control movement of the plunger, the actuating shaft having a pivot member disposed at a distal portion thereof;

a release actuator disposed at a proximal portion of the injection system;

wherein a distal portion of the pivot member is adapted to project radially inwardly when contacted by a sidewall of the first aperture to form a releasable engagement with the syringe plunger; and

wherein the distal portion of the pivot member is adapted to project radially inwardly to disengage the syringe plunger from the actuating shaft when a proximal portion of the pivot member slidingly contacts the release actuator and moves radially inwardly.

23. The injection system of claim 22,

wherein the release actuator is a plate defining a second aperture;

wherein the proximal portion of the pivot member includes a ramped lug projecting outwardly from an outer surface thereof, the latch secured to the sidewall of the first aperture when the actuating shaft and the pivot member are in the engagement position; and

wherein the proximal portion of the pivot member includes a ramped lug projecting outwardly from an outer surface thereof, the ramped lug slidingly engaging with a side wall of the second aperture to drive the proximal end of the pivot member radially inwardly and to drive the distal end of the pivot member radially inwardly such that actuating shaft disengages with the syringe plunger.

24. The injection system of claim 23, wherein the pivot member includes a first pivot member and a second pivot member having a common pivot point, the injection system

further comprising:

a bias member coupled to the first pivot member and the second pivot member, the bias member forcing the first pivot member and the second pivot member radially outwardly such that a distal portion of the first pivot member and the second pivot member are forced radially outwardly.

25. The injection system of claim 24, wherein the bias member is a spring.

26. A method of connecting and disconnecting a syringe plunger from an actuating shaft of an injection system, comprising:

providing the syringe plunger with an aperture at a proximal portion thereof;

providing a syringe body having a distal portion and a proximal portion, the syringe body defining a pumping chamber;

providing an actuating shaft capable of coupling with the syringe plunger, the actuating shaft having a pivot member disposed at a distal portion thereof; and

providing a release actuator proximal to the pumping chamber;

wherein a distal portion of the pivot member projects radially inwardly when contacted by the syringe plunger to form a releasable engagement with the syringe plunger when the actuating shaft and the pivot member are in an engagement position; and

wherein the distal portion of the pivot member projects radially inwardly to disengage the syringe plunger from the actuating shaft when a proximal portion of the pivot member slidingly contacts the release actuator and moves radially inwardly.

27. The method of claim 26,

wherein the release actuator is a plate defining a second aperture;

wherein the proximal portion of the pivot member includes a ramped lug projecting outwardly from an outer surface thereof, the latch secured to the sidewall of the first aperture when the actuating shaft and the pivot member are in the engagement position; and

wherein the proximal portion of the pivot member includes a ramped lug projecting outwardly from an outer surface thereof, the ramped lug slidingly engaging with a side wall of the second aperture to drive the proximal end of the pivot member radially inwardly and to drive the distal end of the pivot member radially inwardly such that actuating shaft disengages with the syringe plunger.

28. The method of claim 27, wherein the pivot member includes a first pivot member and a second pivot member having a common pivot point, the injection system further comprising:

a bias member coupled to the first pivot member and the second pivot member, the bias member forcing a proximal portion of the first pivot member and the second pivot member radially outwardly such that a distal portion of the first pivot member and the second pivot member are forced radially outwardly.

29. The method of claim 28, wherein the bias member is a spring.

30. An injection system comprising:

a syringe body having a distal portion and a proximal portion, the syringe body defining a pumping chamber;

a syringe plunger located in the pumping chamber and adapted for reciprocal motion within the pumping chamber;

an actuating shaft coupled to the syringe plunger and movable through the syringe body to control movement of the syringe plunger;

a releasable connection mechanism adapted to make a releasable connection with the actuating shaft and the syringe plunger, the releasable connection comprising:

a ferrous metal member disposed on one of the syringe plunger and the actuating shaft; and

a permanent magnet disposed on the other one of the syringe plunger and the actuating shaft;

wherein the syringe plunger is in an engaged position with the actuating shaft when the permanent magnet is magnetically attached to the ferrous metal member.

31. The syringe plunger of claim 30, wherein the syringe plunger includes a plunger support member and a wiper, wherein the wiper is attached to the plunger support member, wherein the ferrous metal is disposed on one of the plunger support member and the actuating shaft, and wherein a zero insertion force is required to engage the syringe plunger with the actuating shaft.

32. An injection system comprising:

a syringe body having a distal portion and a proximal portion, the syringe body

defining a pumping chamber;

a syringe plunger located in the pumping chamber and adapted for reciprocal motion within the pumping chamber;

an actuating shaft coupled to the syringe plunger and movable through the syringe body to control movement of the syringe plunger; and

a releasable connection mechanism adapted to make a releasable connection with the actuating shaft and the syringe plunger, the releasable connection comprising:

an electromagnet disposed on one of the syringe plunger and the actuating shaft; and

a ferrous metal member disposed on the other one of the syringe plunger and the actuating shaft;

wherein the syringe plunger is in an engaged position with the actuating shaft when the electromagnet is magnetically attached to the ferrous metal member.

33. The injection system of claim 32, wherein the syringe plunger includes a plunger support member and a wiper, wherein the wiper is attached to the plunger support member, wherein the ferrous metal member is disposed on one of the plunger support member and the actuating shaft, and wherein a zero insertion force is required to engage the syringe plunger with the actuating shaft.

34. An injection system comprising:

a syringe body having a distal portion and a proximal portion, the syringe body defining a pumping chamber;

a syringe plunger located in the pumping chamber and adapted for reciprocal motion within the pumping chamber;

an actuating shaft coupled to the syringe plunger and movable through the syringe body to control movement of the syringe plunger; and

a releasable connection mechanism adapted to make a releasable connection with the actuating shaft and the syringe plunger, the releasable connection comprising:

an electromagnet disposed on one of the syringe plunger and the actuating shaft; and

a permanent magnet disposed on the other one of the syringe plunger and the actuating shaft;

wherein the syringe plunger is in an engaged position with the actuating shaft when

the electromagnet is magnetically attached to the permanent magnet.

35. The injection system of claim 34, wherein the syringe plunger includes a plunger support member and a wiper, wherein the wiper is attached to the plunger support member, wherein the electromagnet is disposed on one of the plunger support member and the actuating shaft, and wherein a zero insertion force is required to engage the syringe plunger with the actuating shaft.

36. An injection system comprising:

a syringe body having a distal portion and a proximal portion, the syringe body defining a pumping chamber;

a syringe plunger located in the pumping chamber and adapted for reciprocal motion within the pumping chamber;

an actuating shaft coupled to the syringe plunger and movable through the syringe body to control movement of the syringe plunger; and

a releasable connection mechanism adapted to make a releasable connection with the actuating shaft and the syringe plunger, the releasable connection comprising:

a first permanent magnet disposed on the syringe plunger; and

a second permanent magnet disposed on the actuating shaft;

wherein the syringe plunger is in an engaged position with the actuating shaft when the first permanent magnet is magnetically attached to the second permanent magnet.

37. The injection system of claim 36, wherein the syringe plunger includes a plunger support member and a wiper, wherein the wiper is attached to the plunger support member, wherein the first permanent magnet is disposed on the plunger support member, and wherein a zero insertion force is required to engage the syringe plunger with the actuating shaft.

38. An injection system comprising:

a syringe body having a distal portion and a proximal portion, the syringe body defining a pumping chamber;

a syringe plunger located in the pumping chamber and adapted for reciprocal motion between a position proximate to the proximal portion and the distal portion, the syringe plunger having first aperture disposed at a proximal portion thereof; and

an actuating shaft capable of coupling to the plunger and movable through the syringe body to control movement of the plunger, the actuating shaft having a movable first collet member and a movable second collet member disposed at a distal portion thereof;

a release actuator disposed at a proximal portion of the injection system;

wherein the distal portions of the movable collet members are adapted to project radially inwardly when contacted by a sidewall of the first aperture to form a releasable engagement with the syringe plunger; and

wherein the distal portions of the movable collet members are adapted to project radially inwardly to disengage the syringe plunger from the actuating shaft when a proximal portion of the movable collet members slidably contact the release actuator and move radially inwardly.

39. The injection system of claim 38,

wherein the release actuator is a plate defining a second aperture;

wherein a proximal portion of the movable collet members include ramped detachment members projecting outwardly, the detachment members capable of slidably engaging a side wall of the second aperture to drive the proximal end of the movable collet members radially inwardly and to drive the distal end of the movable collet members radially inwardly such that actuating shaft disengages with the syringe plunger.

40. The injection system of claim 39, wherein the movable collet members have a common pivot point, the injection system further comprising:

at least one bias member coupled to the movable first collet member and the movable second collet member, the at least one bias member forcing the movable first collet member and the movable second collet member radially outwardly such that a distal portion of the movable collet members are forced radially outwardly.

41. The injection system of claim 40, wherein the at least one bias member is a spring.

42. A method of connecting and disconnecting a syringe plunger from an actuating shaft of an injection system, comprising:

providing the syringe plunger with an aperture at a proximal portion thereof;

providing a syringe body having a distal portion and a proximal portion, the syringe

body defining a pumping chamber;

providing an actuating shaft capable of coupling with the syringe plunger, the actuating shaft having a movable first collet member and a movable second collet member disposed at a distal portion thereof; and

providing a release actuator proximal to the pumping chamber;

wherein a distal portion of the movable collet members project radially inwardly when contacted by the syringe plunger to form a releasable engagement with the syringe plunger when the actuating shaft and the movable collet members are in an engagement position; and

wherein the distal portion of the movable collet members project radially inwardly to disengage the syringe plunger from the actuating shaft when a proximal portion of the movable collet members slidably contacts the release actuator and moves radially inwardly.

43. The method of claim 42,

wherein the release actuator is a plate defining a second aperture;

wherein the proximal portion of the movable collet members include a ramped detachment member projecting outwardly, the ramped detachment member capable of slidably engaging with a side wall of the second aperture to drive the proximal end of the movable collet members radially inwardly and to drive the distal end of the movable collet members radially inwardly such that actuating shaft disengages with the syringe plunger.

44. The method of claim 43, wherein the movable collet members include a movable first collet member and a movable second collet member having a common pivot point, the injection system further comprising:

at least one bias member coupled to the movable first collet member and the movable second collet member, the at least one bias member forcing a proximal portion of the movable first collet member and the movable second collet member radially outwardly such that a distal portion of the movable first collet member and the movable second collet member are forced radially outwardly.

45. The method of claim 44, wherein the bias member is a spring.

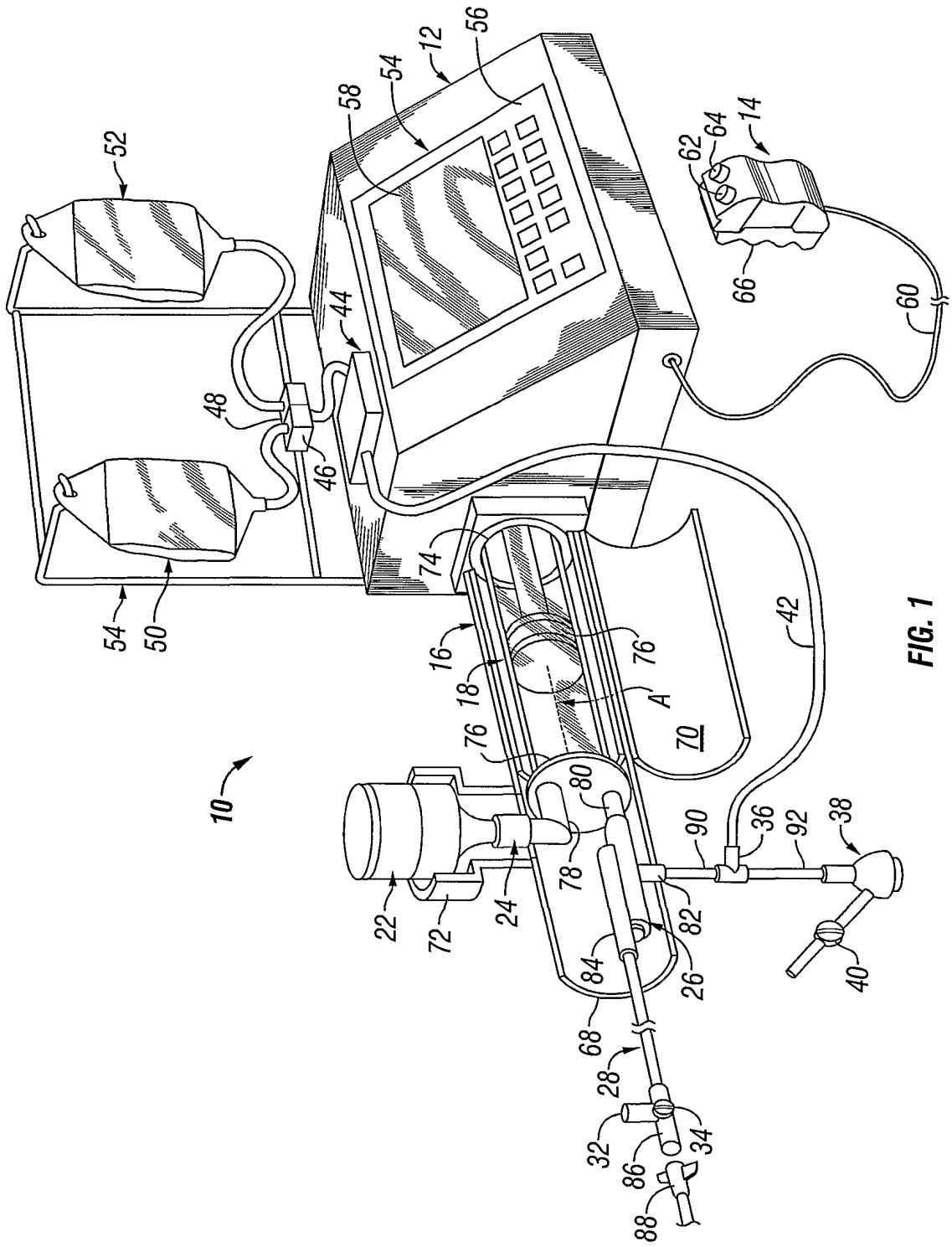
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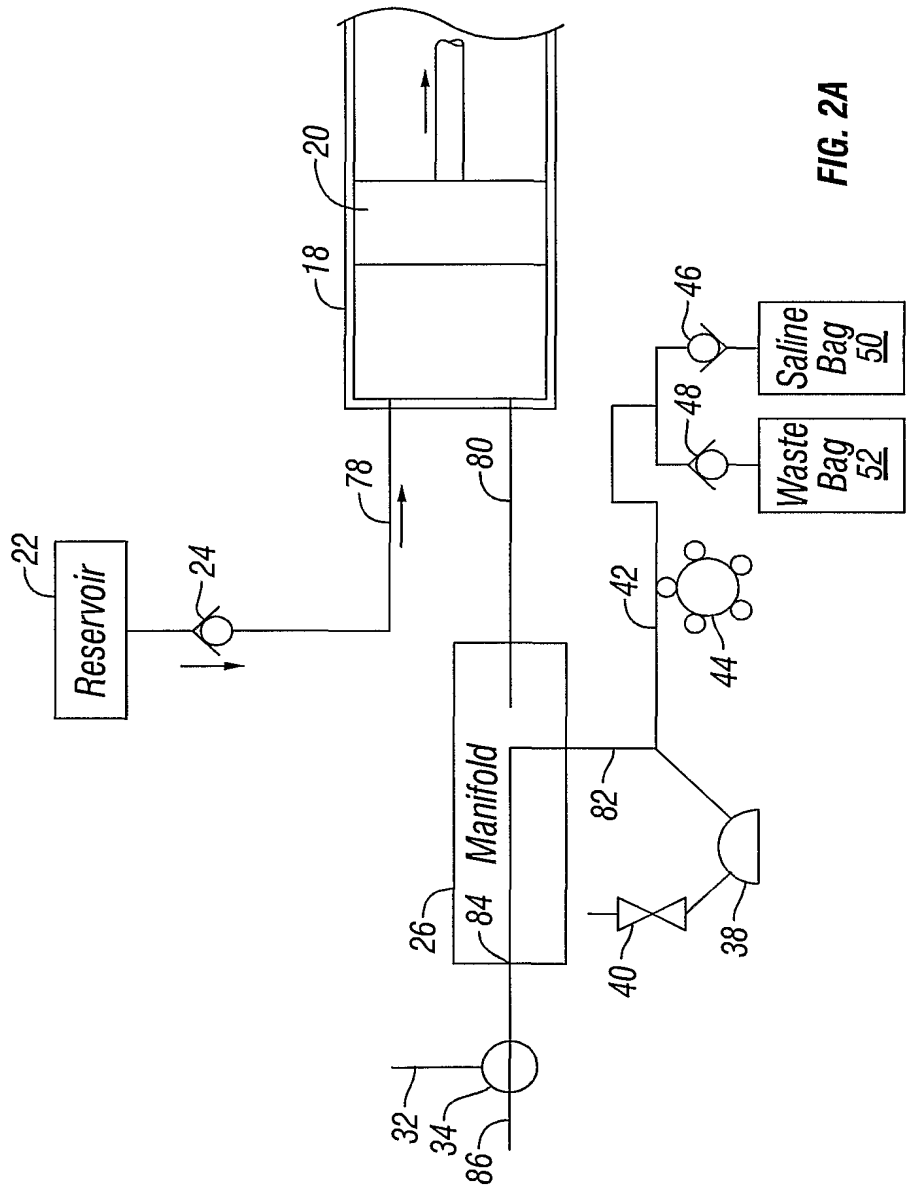
FIG. 1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Manifold
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Saline Bag 50
Waste Bag 52
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34
86

FIG. 2A

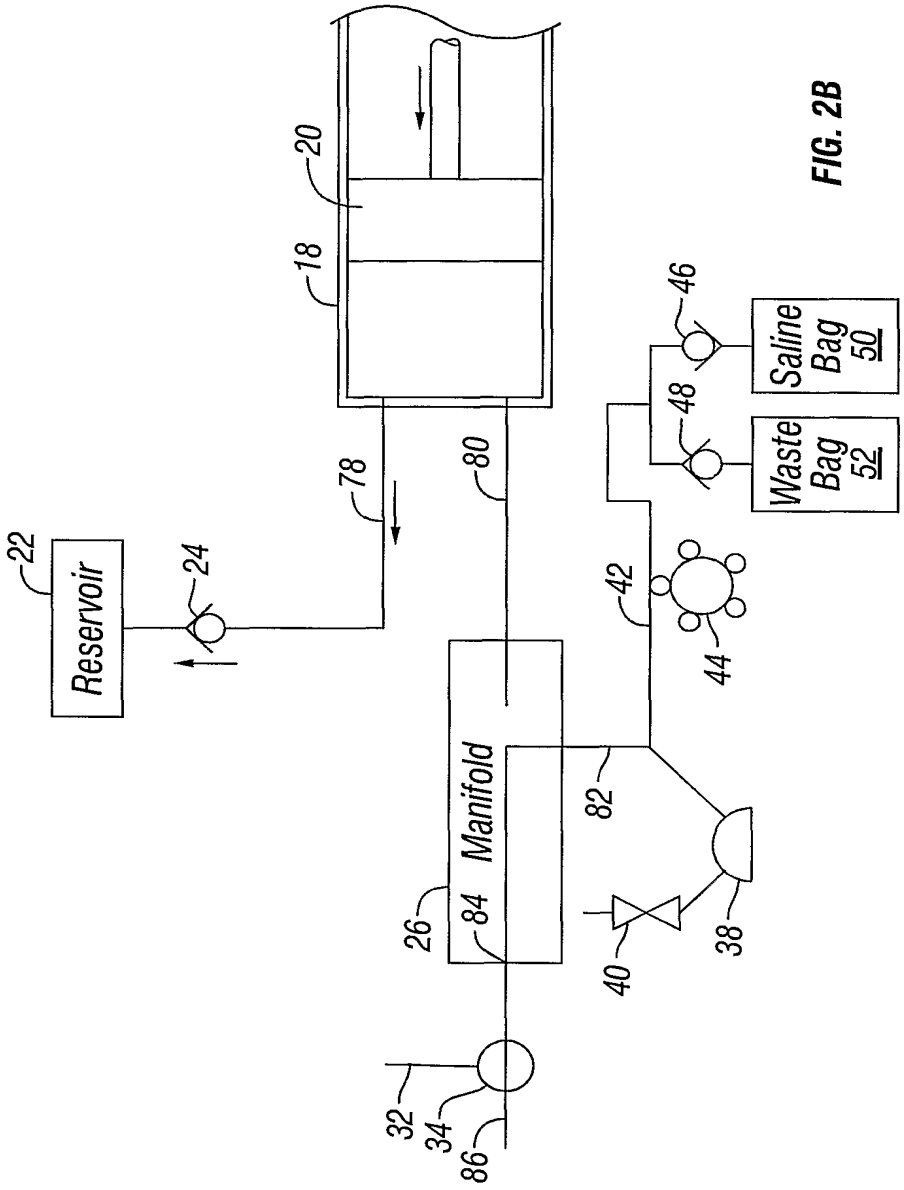
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FIG. 2B

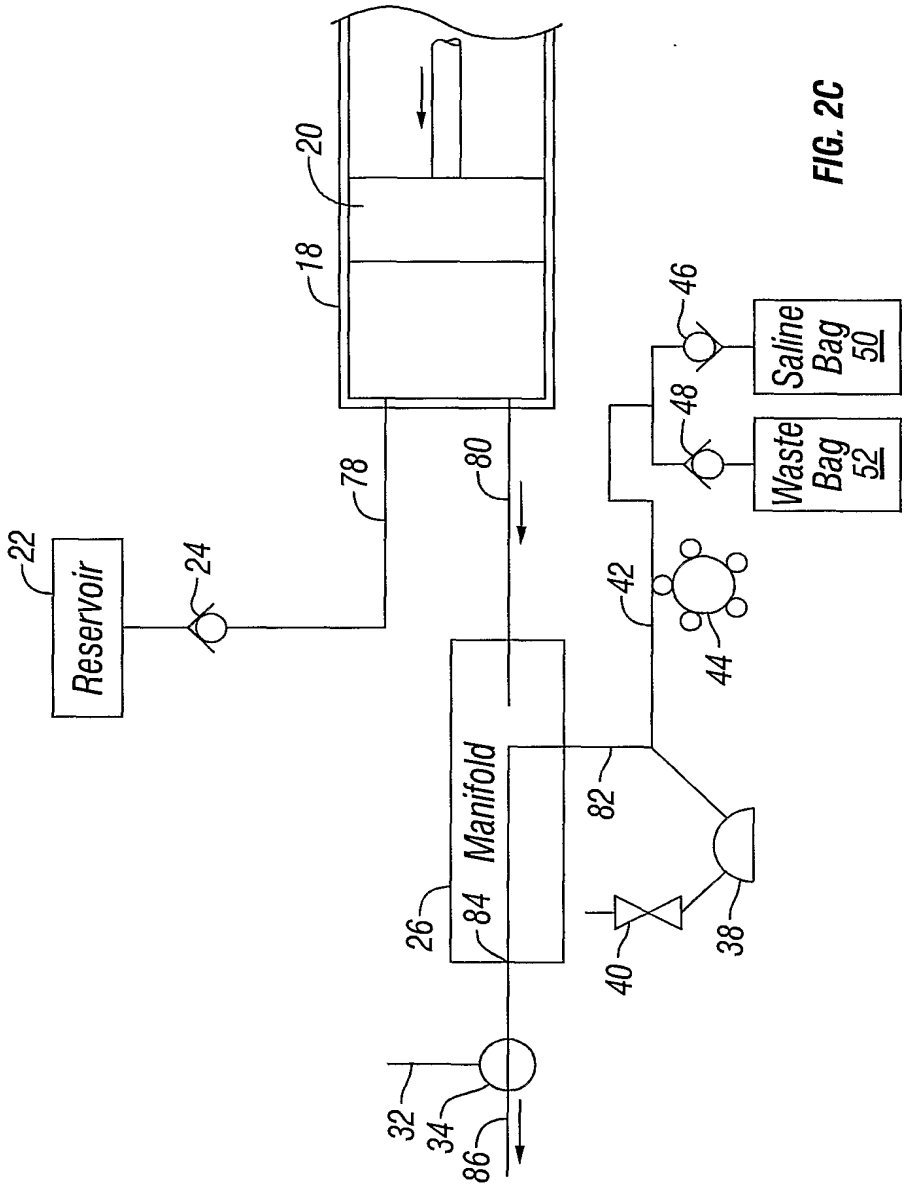
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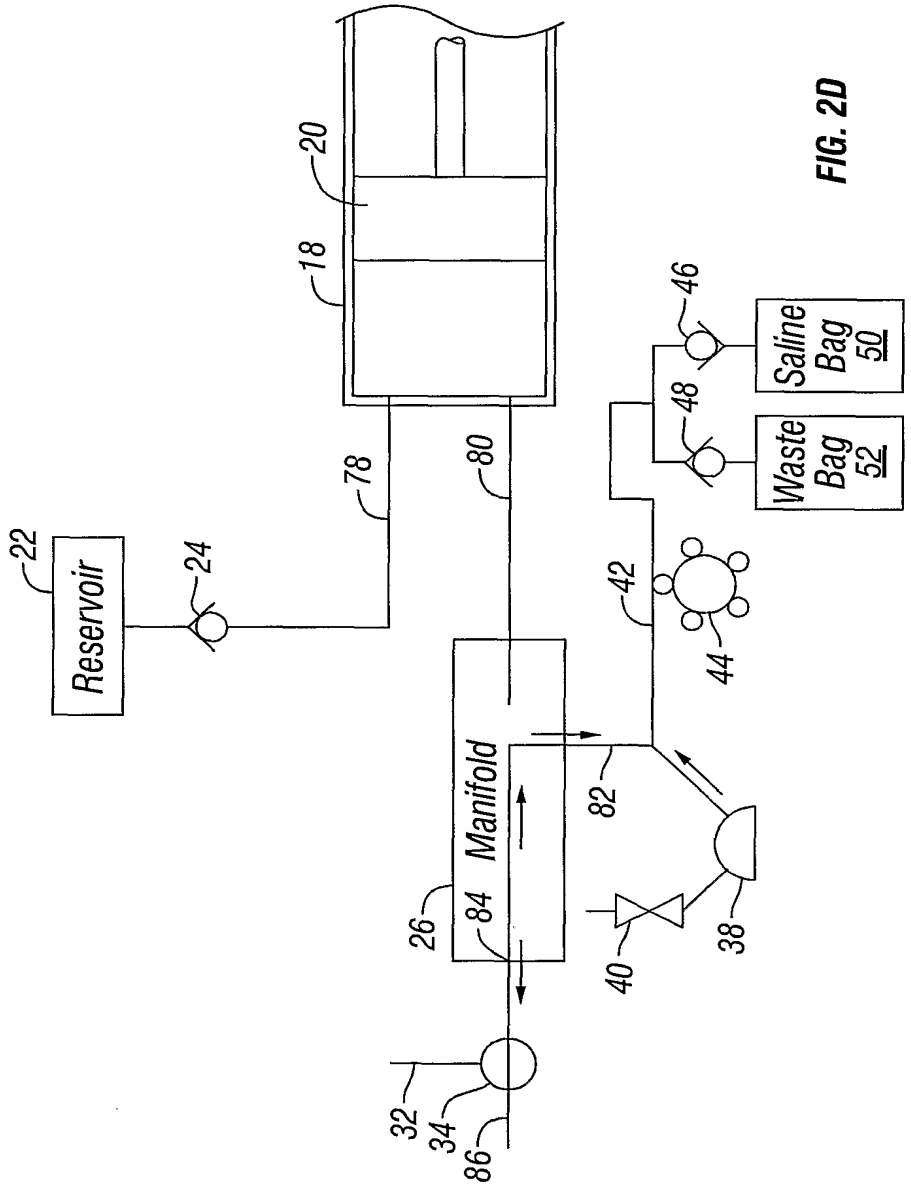
FIG. 2C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Waste Bag 52
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FIG. 2D

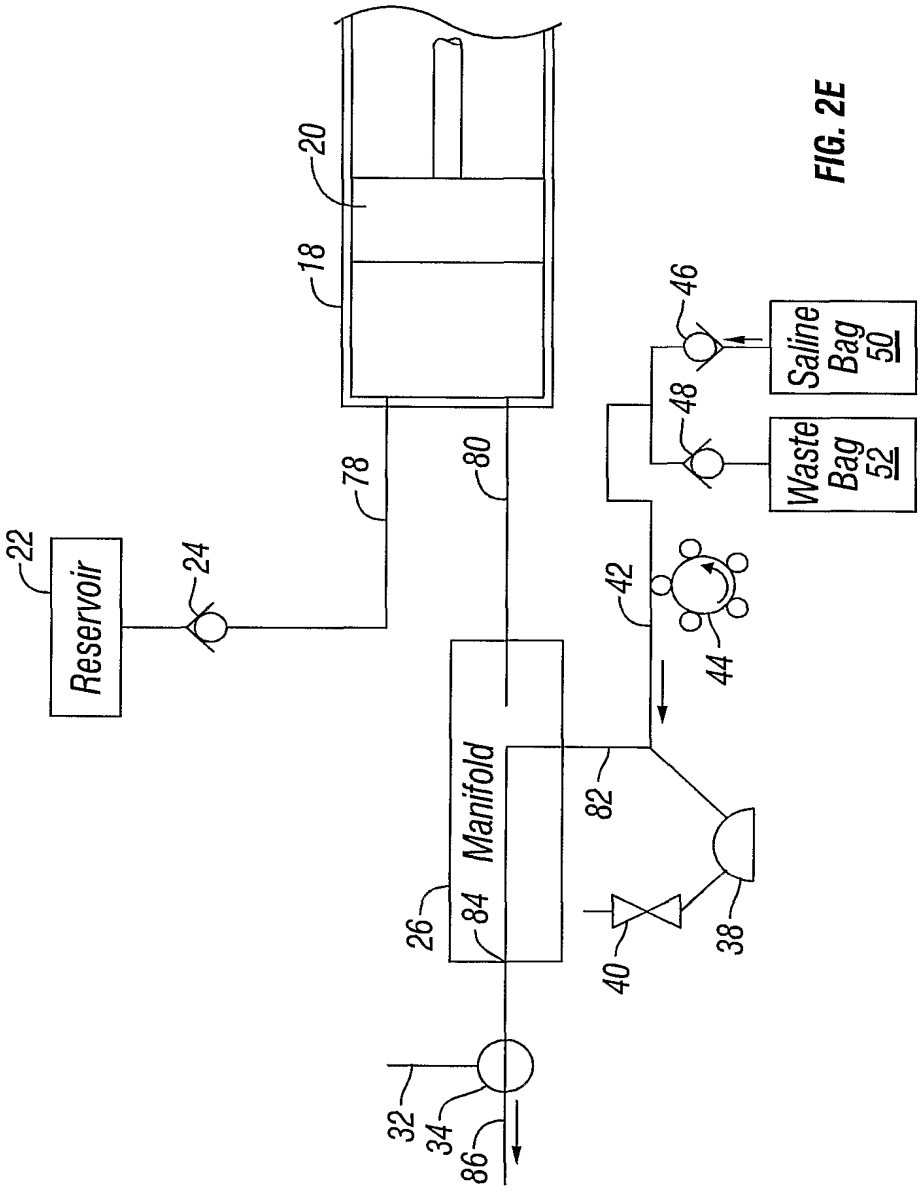
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FIG. 2E

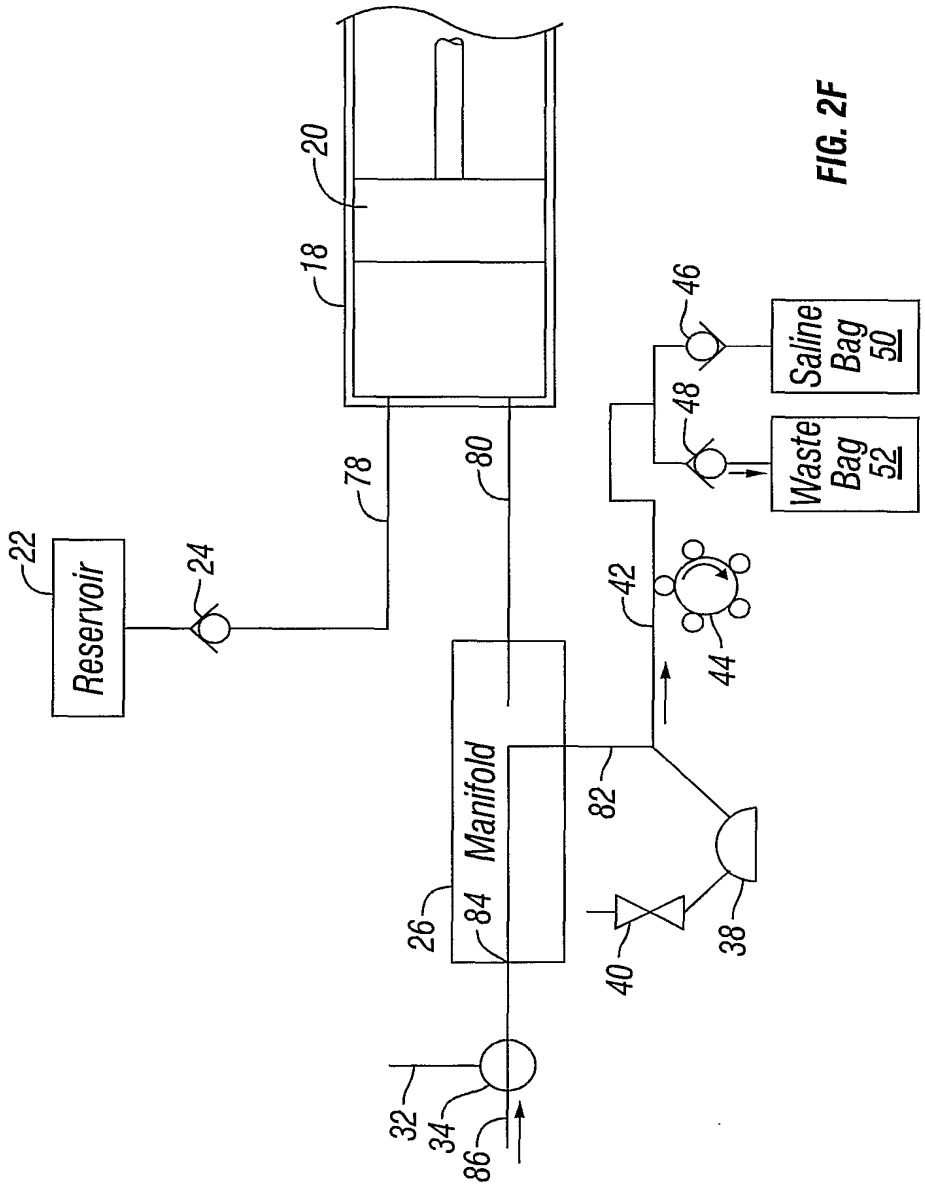
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FIG. 2F

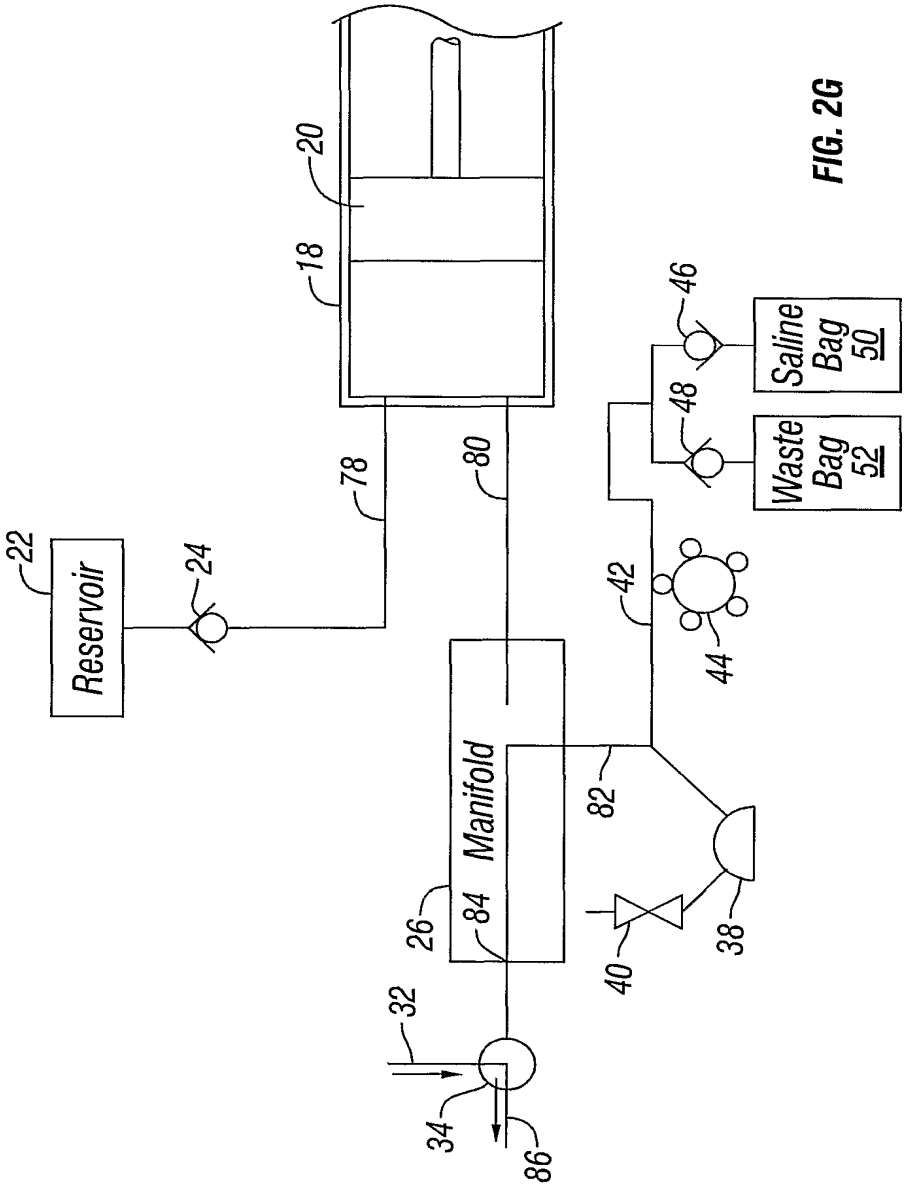
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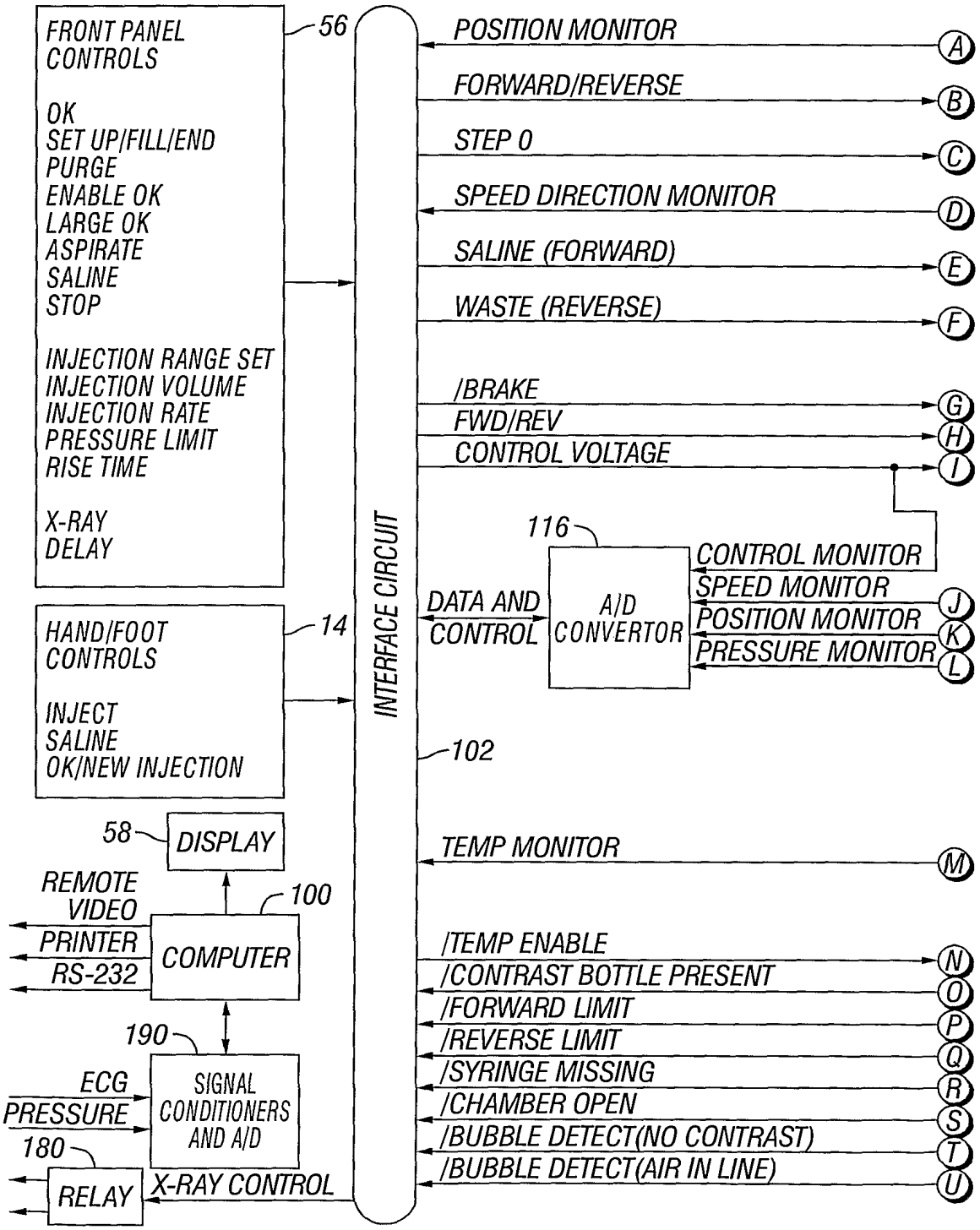
FIG. 2G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ASPIRATE
SALINE
STOP
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INJECTION RATE
PRESSURE LIMIT
RISE TIME
X-RAY
DELAY
56
HAND/FOOT CONTROLS
INJECT
SALINE
OK/NEW INJECTION
14
58
DISPLAY
REMOTE VIDEO
PRINTER
RS-232
COMPUTER
100
190
ECG
PRESSURE
SIGNAL CONDITIONERS AND A/D
180
RELAY
X-RAY CONTROL
INTERFACE CIRCUIT
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POSITION MONITOR
FORWARD/REVERSE
STEP 0
SPEED DIRECTION MONITOR
SALINE (FORWARD)
WASTE (REVERSE)
/BRAKE
FWD/REV
CONTROL VOLTAGE
116
DATA AND CONTROL
A/D CONVERTOR
CONTROL MONITOR
SPEED MONITOR
POSITION MONITOR
PRESSURE MONITOR
TEMP MONITOR
/TEMP ENABLE
/CONTRAST BOTTLE PRESENT
/FORWARD LIMIT
/REVERSE LIMIT
/SYRINGE MISSING
/CHAMBER OPEN
/BUBBLE DETECT(NO CONTRAST)
/BUBBLE DETECT(AIR IN LINE)
A
B
C
D
E
F
G
H
I
J
K
L
M
N
O
P
Q
R
S
T
U

FIG. 3A

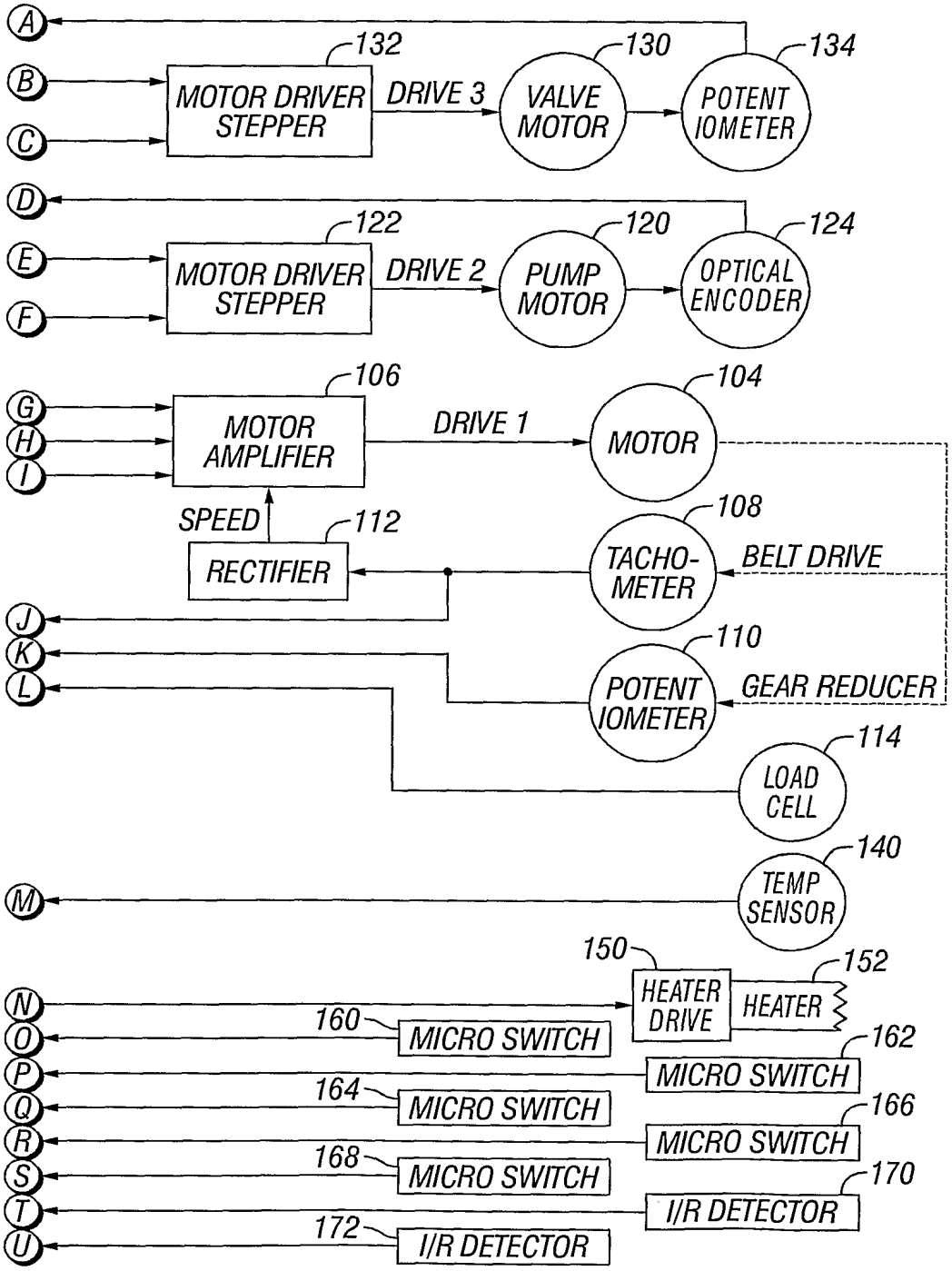

A
B
C
D
E
F
G
H
I
J
K
L
M
N
O
P
Q
R
S
T
U
MOTOR DRIVER STEPPER
132
DRIVE 3
VALVE MOTOR
130
POTENT IOMETER
134
MOTOR DRIVER STEPPER
122
DRIVE 2
PUMP MOTOR
120
OPTICAL ENCODER
124
MOTOR AMPLIFIER
106
DRIVE 1
MOTOR
104
SPEED
RECTIFIER
112
TACHO-METER
108
BELT DRIVE
POTENT IOMETER
110
GEAR REDUCER
LOAD CELL
114
TEMP SENSOR
140
HEATER DRIVE
150
HEATER
152
MICRO SWITCH
160
MICRO SWITCH
162
MICRO SWITCH
164
MICRO SWITCH
166
I/R DETECTOR
168
I/R DETECTOR
170
172

FIG. 3B

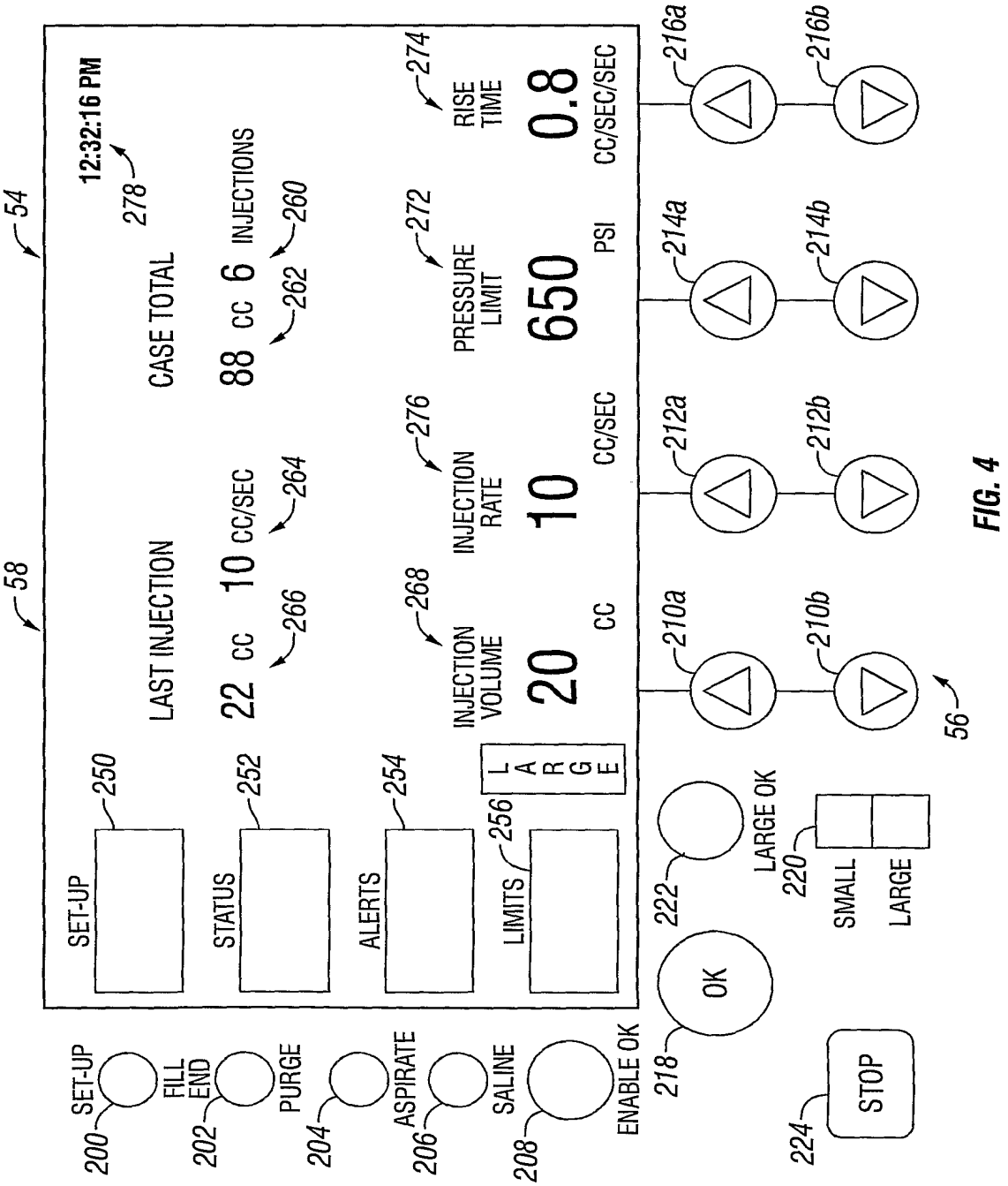

54
58
12:32:16 PM
278
LAST INJECTION
CASE TOTAL
22 cc 10 CC/SEC
88 cc 6 INJECTIONS
266
264
262
260
INJECTION VOLUME
INJECTION RATE
PRESSURE LIMIT
RISE TIME
268
276
272
274
20 cc
10 CC/SEC
650 PSI
0.8 CC/SEC/SEC
SET-UP
STATUS
ALERTS
LIMITS
250
252
254
256
L A R G E
210a
210b
212a
212b
214a
214b
216a
216b
56
SET-UP
FILL END
PURGE
ASPIRATE
SALINE
ENABLE OK
200
202
204
206
208
218
OK
222
LARGE OK
220
SMALL
LARGE
224
STOP

FIG. 4

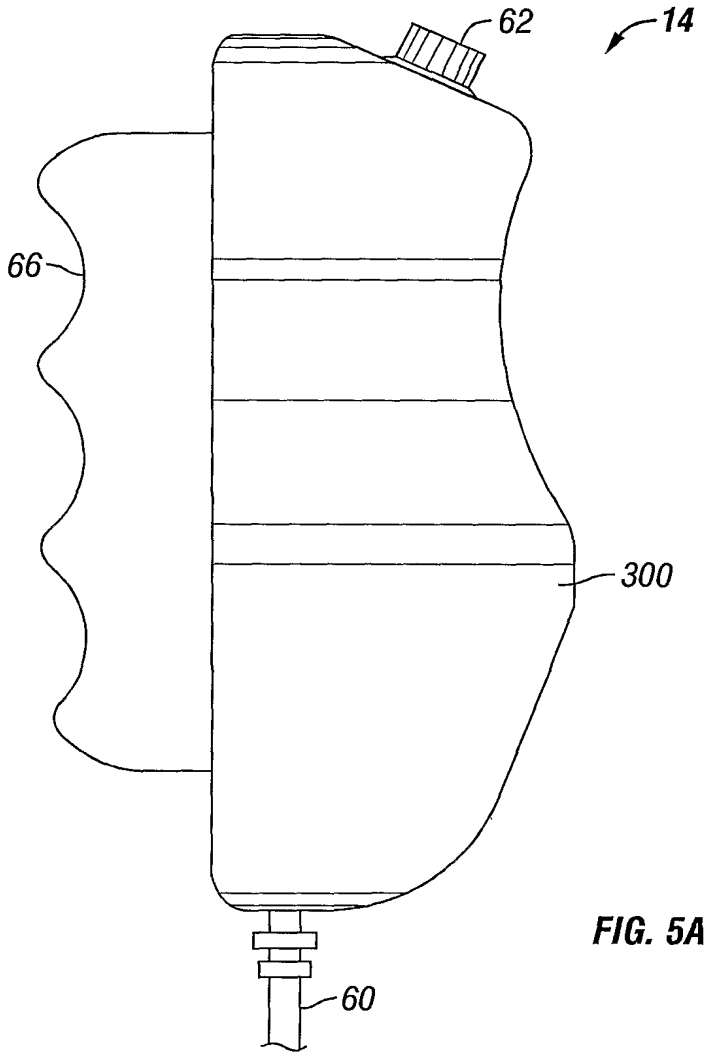


FIG. 5A

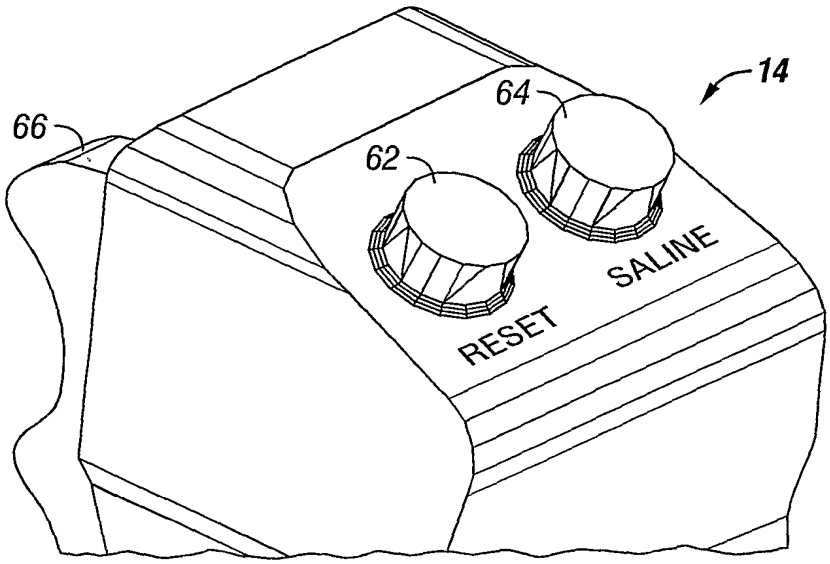


FIG. 5B

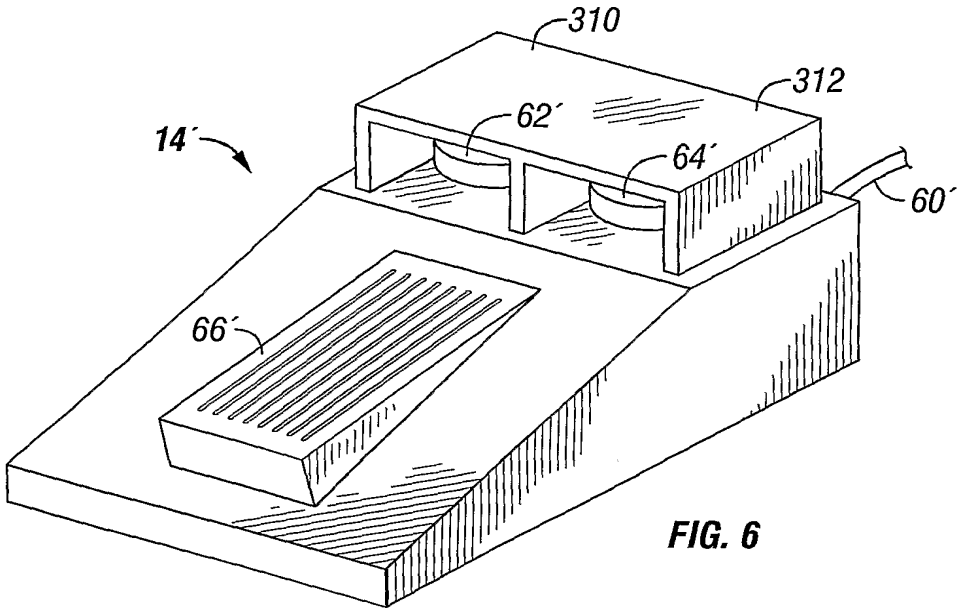


FIG. 6

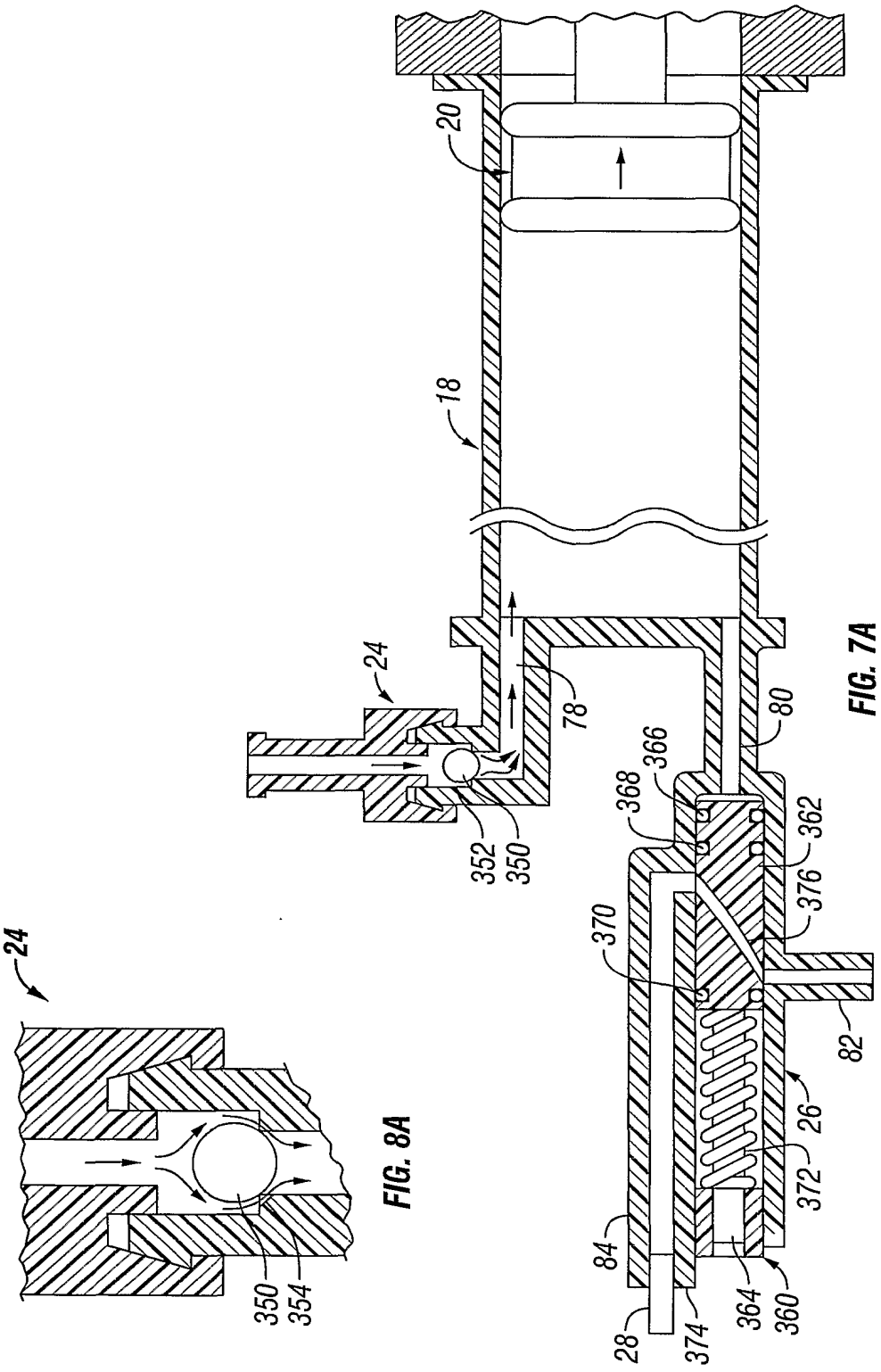

20
18
24
78
80
352
350
366
368
362
376
370
82
26
372
84
364
360
28
374
24
350
354

FIG. 7A

FIG. 8A

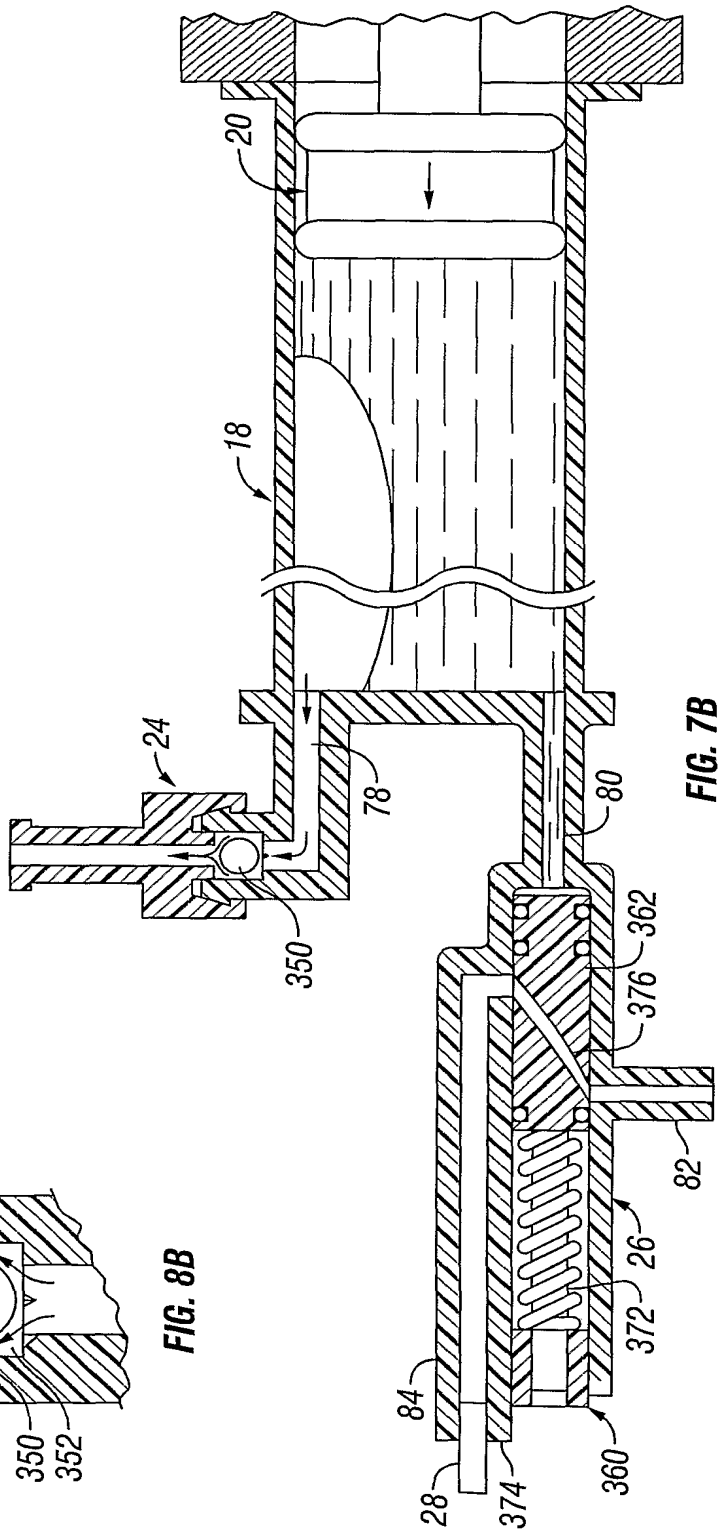


FIG. 7B

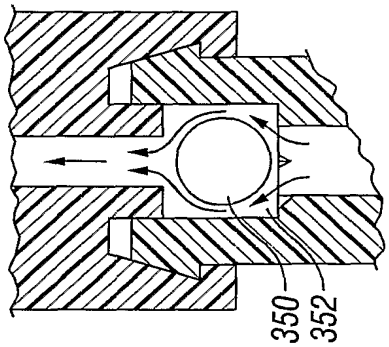


FIG. 8B

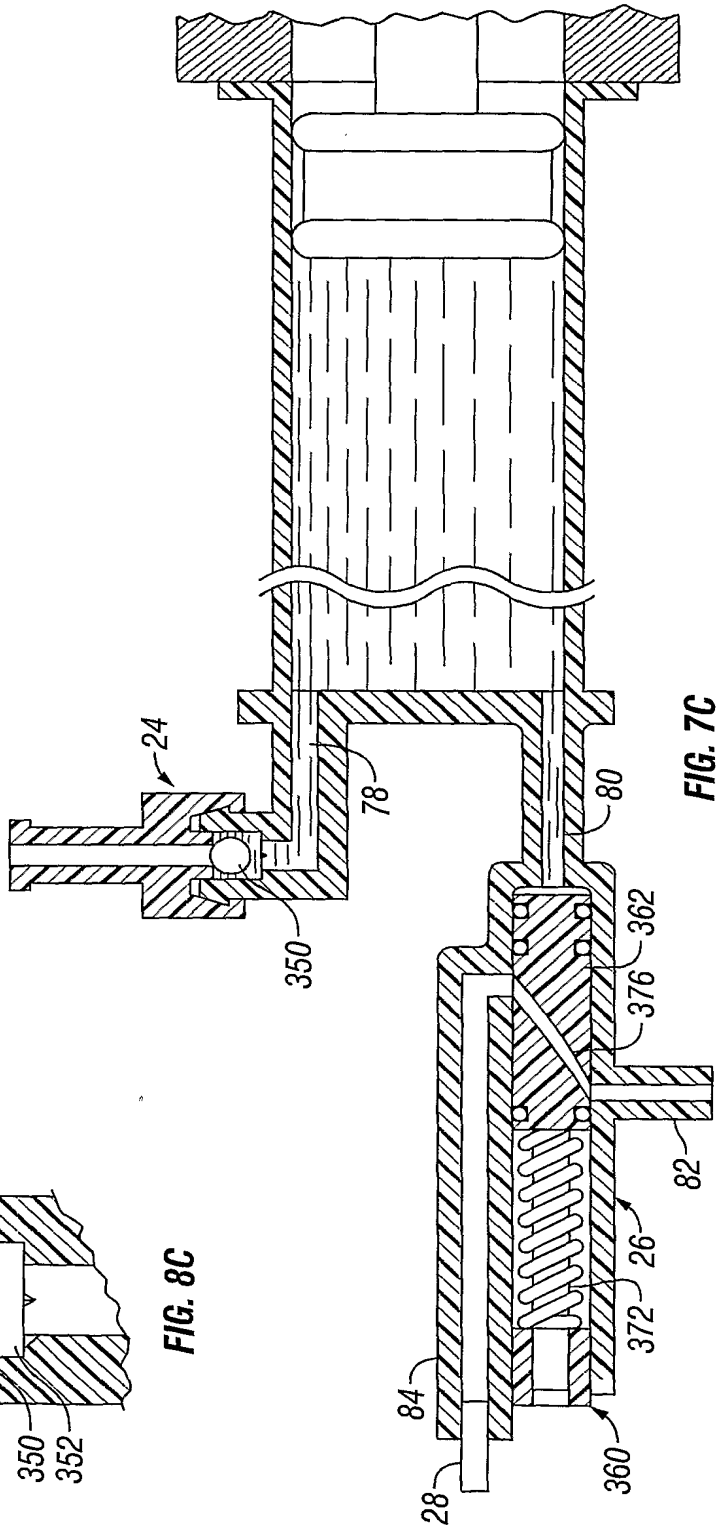


FIG. 7C

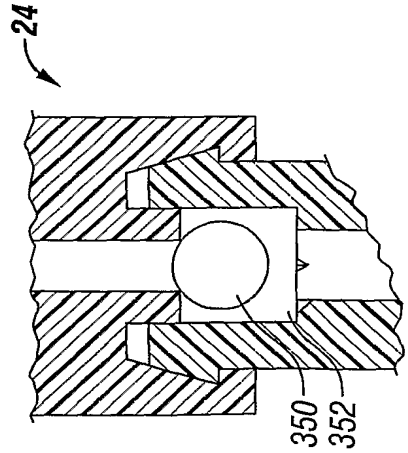


FIG. 8C

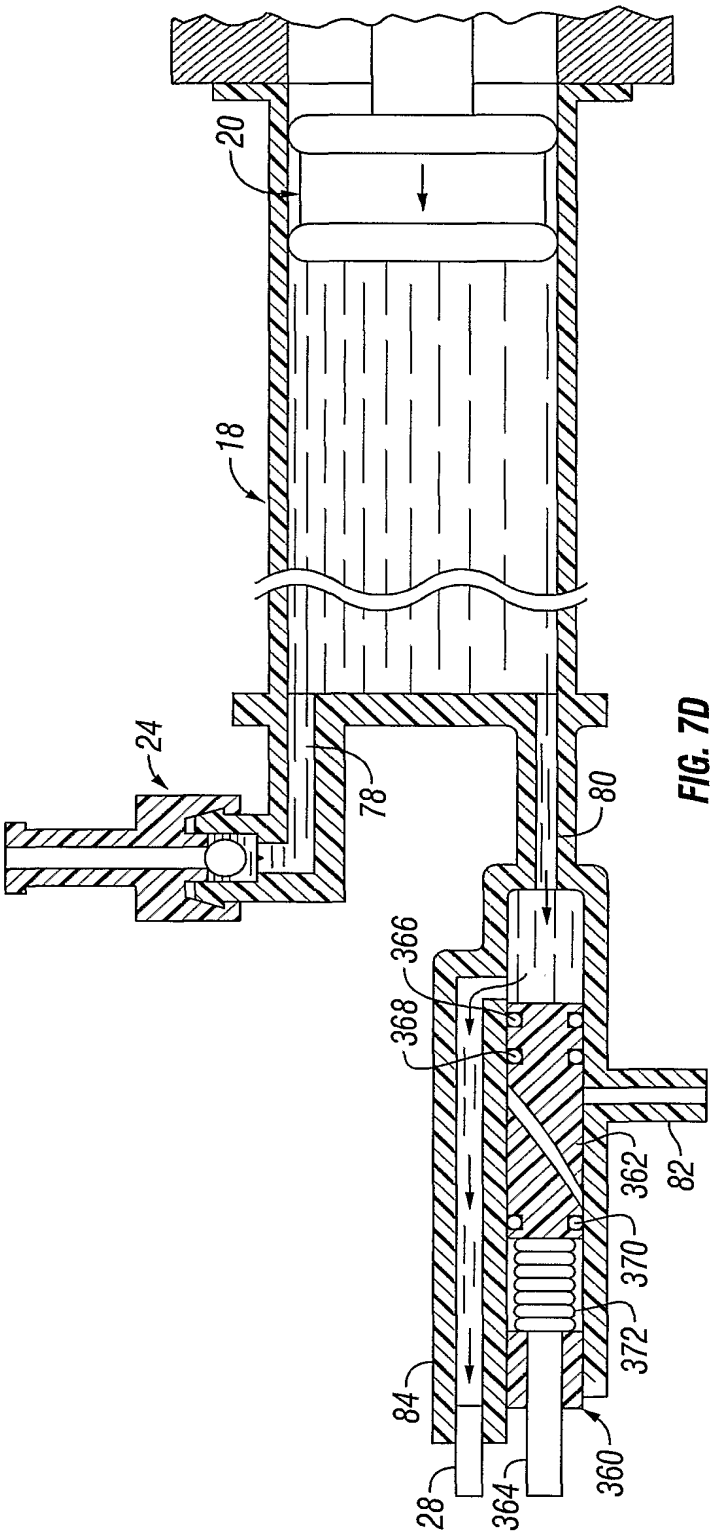


FIG. 7D

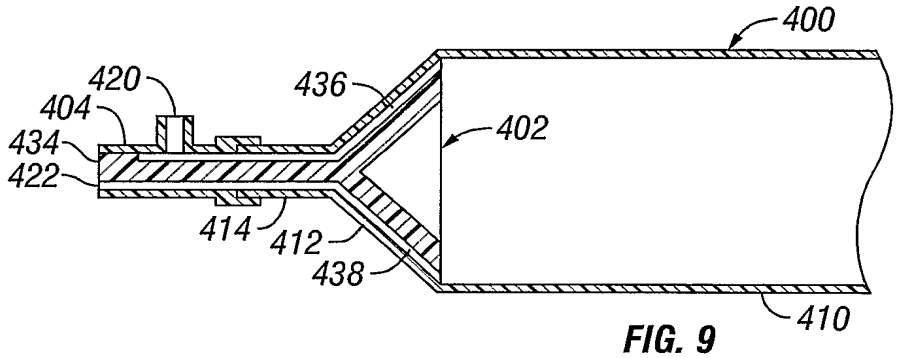


FIG. 9

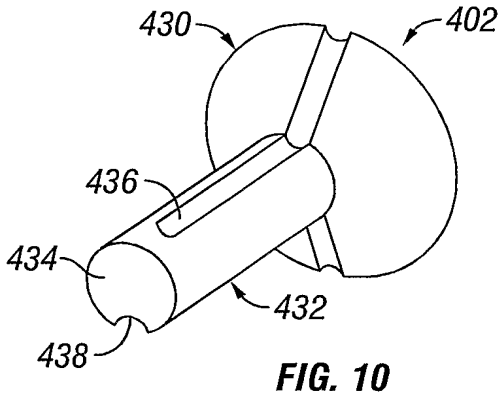


FIG. 10

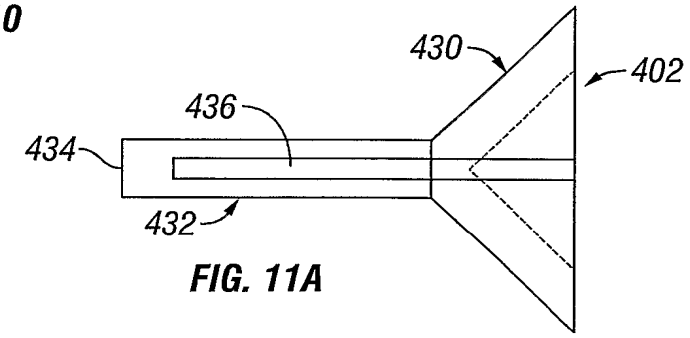


FIG. 11A

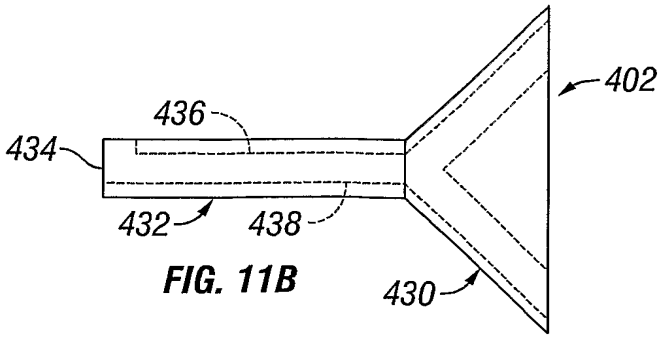


FIG. 11B

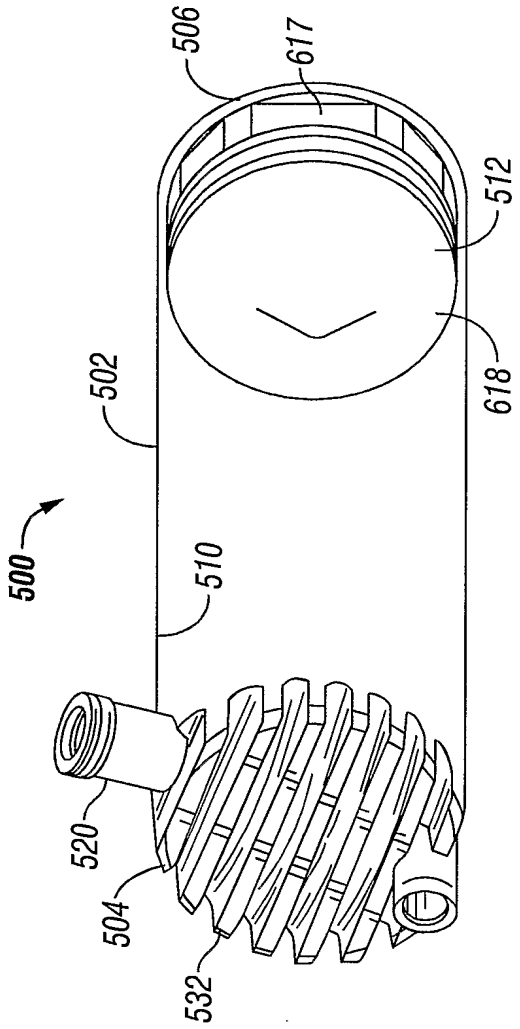

506
617
512
618
502
500
510
520
504
532

FIG. 12

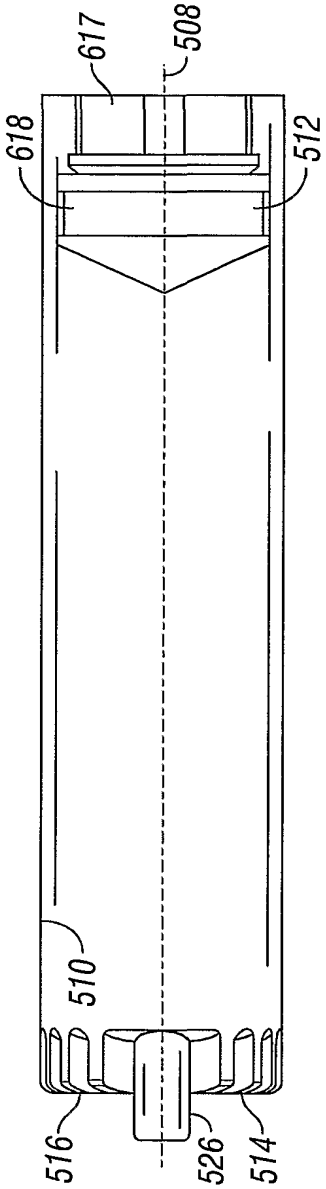

617
508
618
512
510
516
526
514

FIG. 13

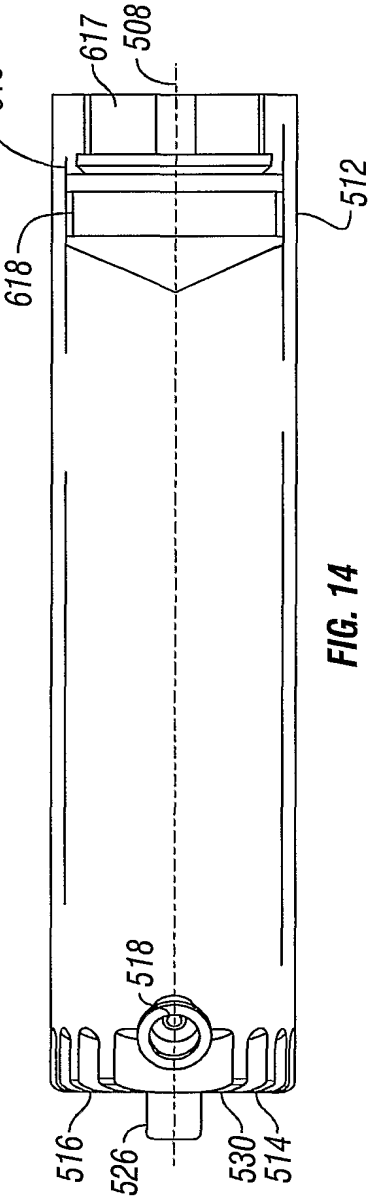


FIG. 14

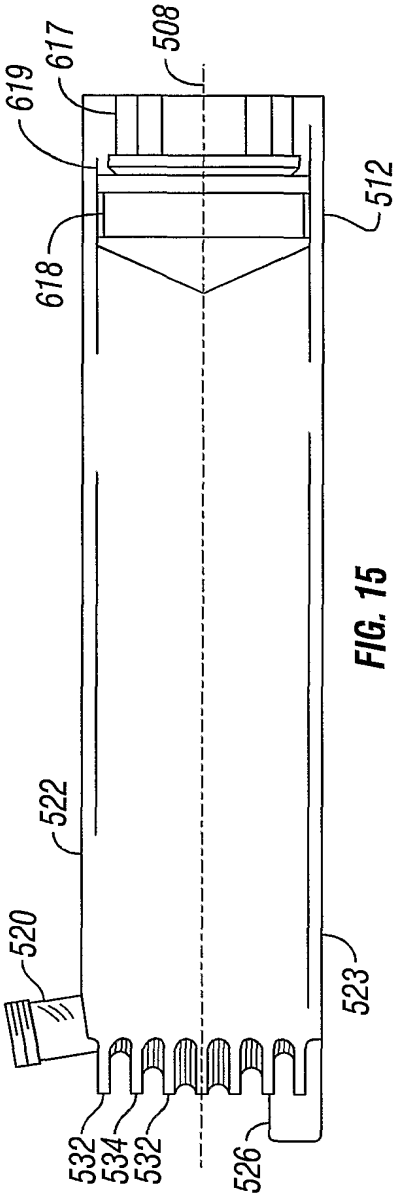


FIG. 15

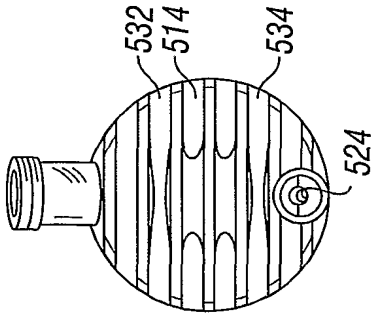


FIG. 16

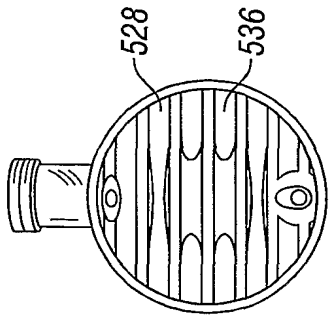
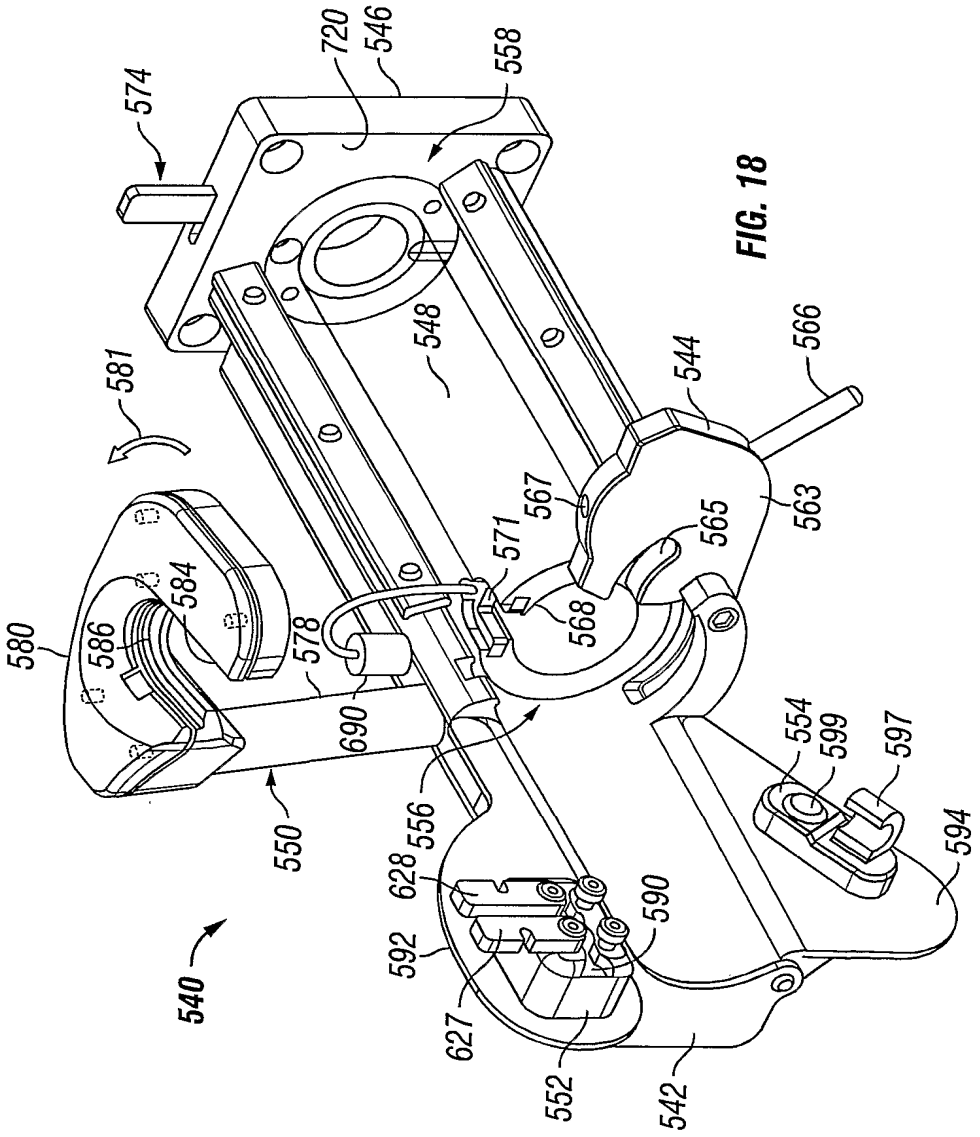


FIG. 17


720
546
558
574
548
581
544
566
567
563
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584
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597
556
550
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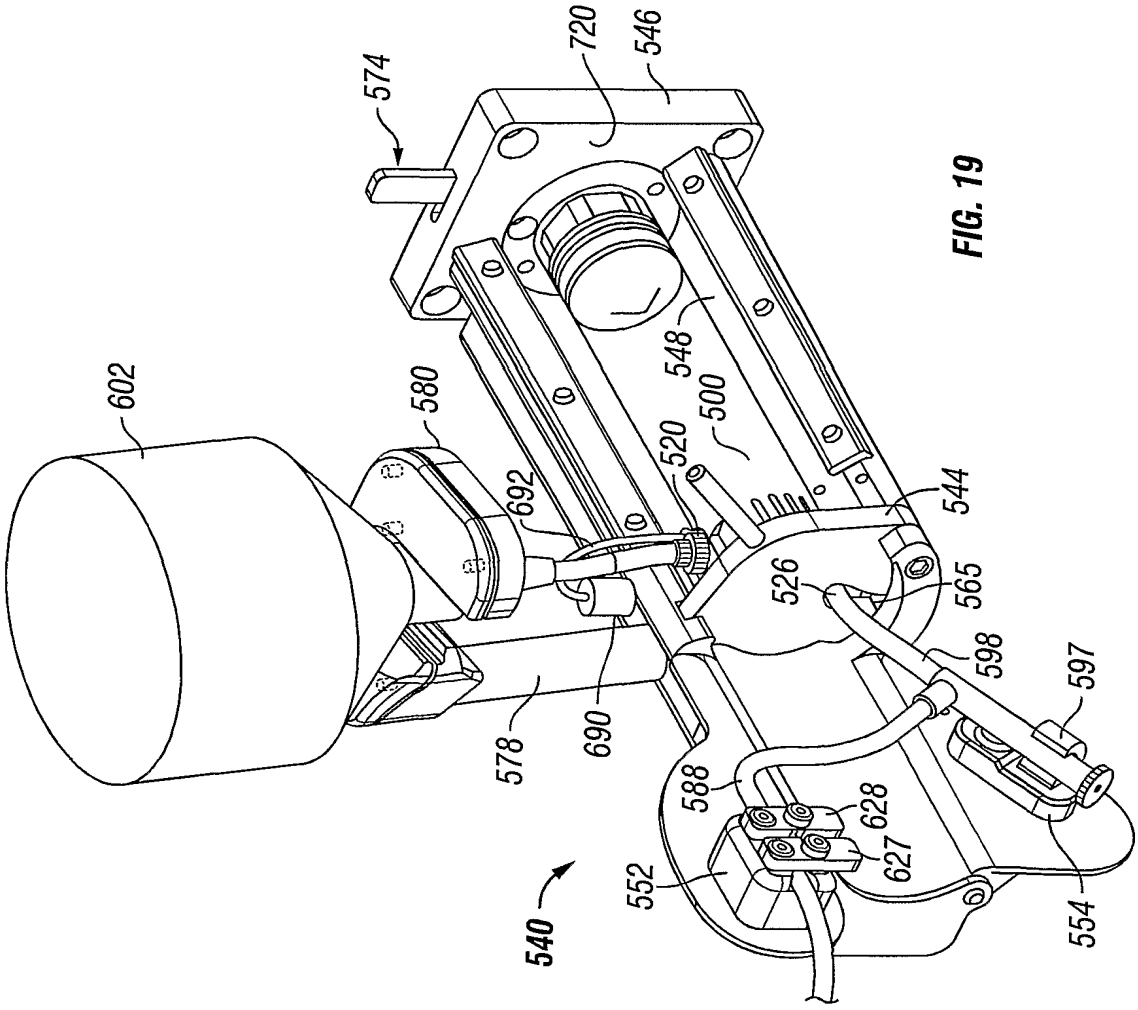
594
590
592
540
627
552
542

FIG. 18


574
720
546
548
500
520
580
602
692
544
526
565
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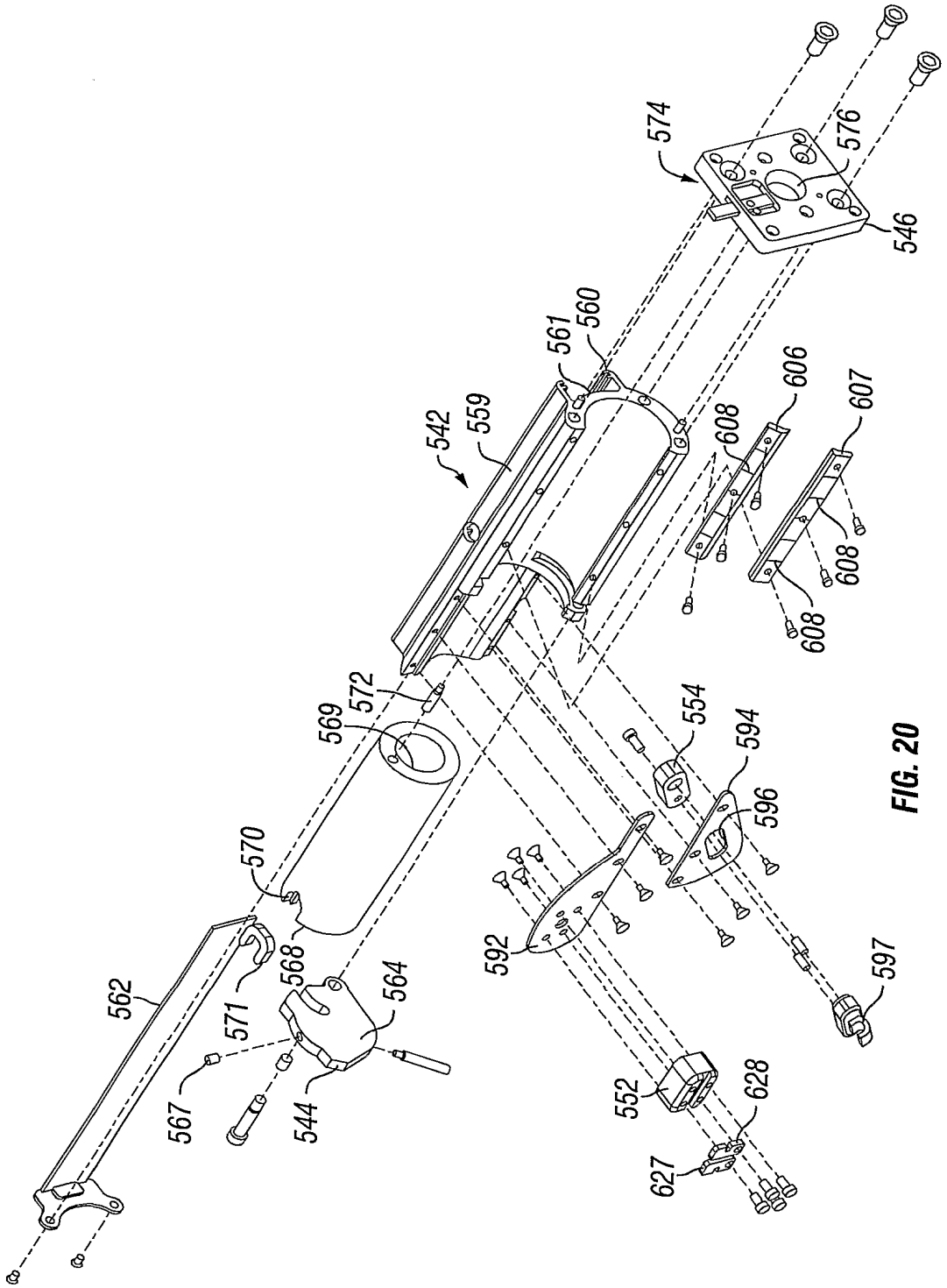
597
578
690
588
628
627
552
554
540

FIG. 19


574
576
546
561
560
542
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606
608
607
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608
608
554
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596
572
569
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597
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627

FIG. 20

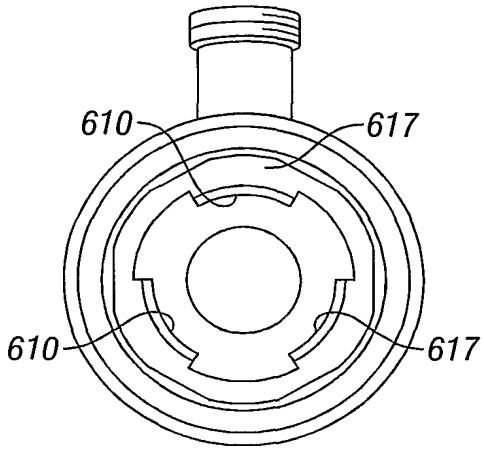


FIG. 21

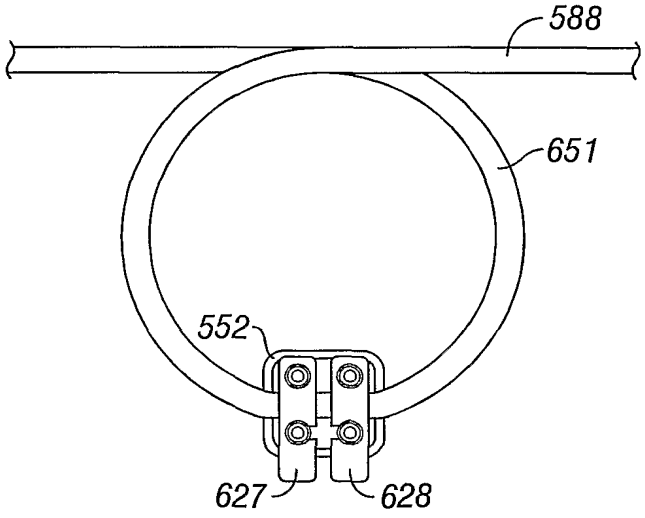


FIG. 22

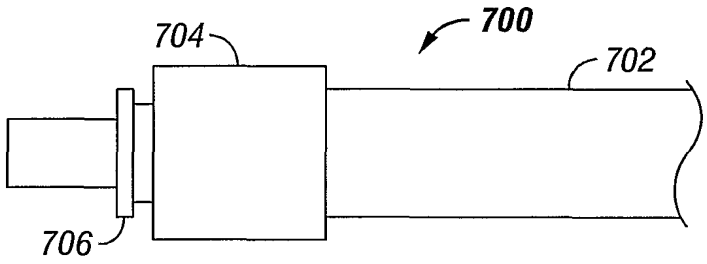


FIG. 23

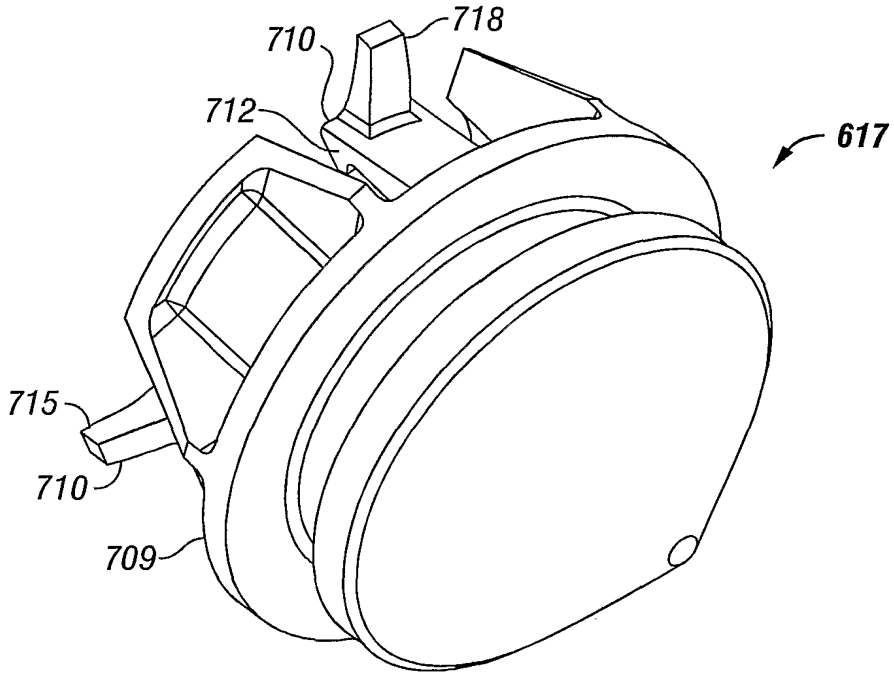


FIG. 24A

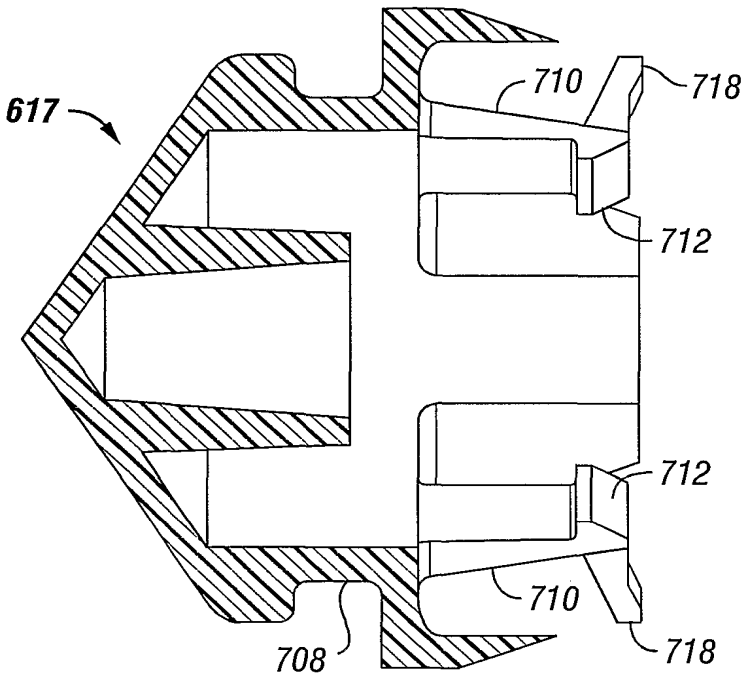


FIG. 24B

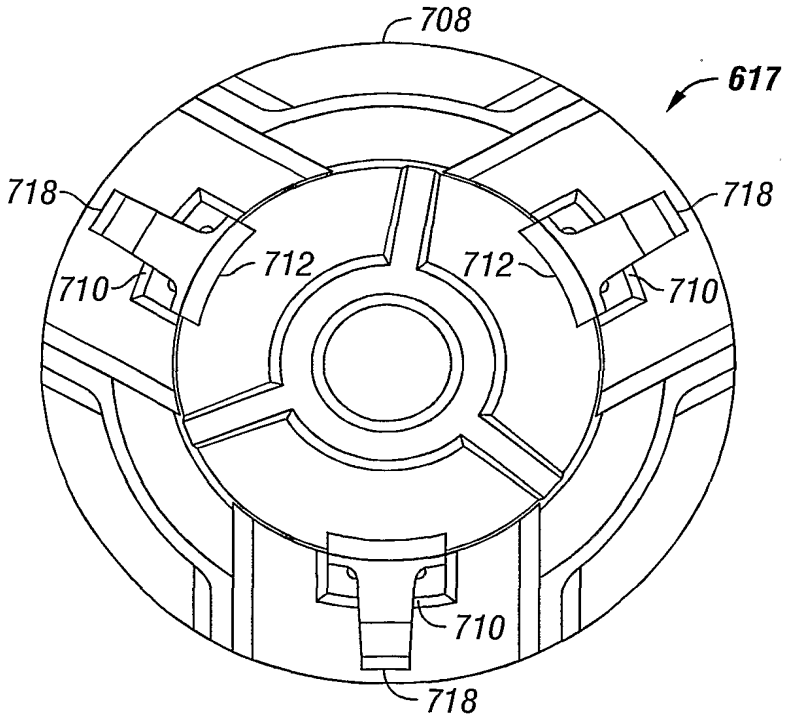


FIG. 24C

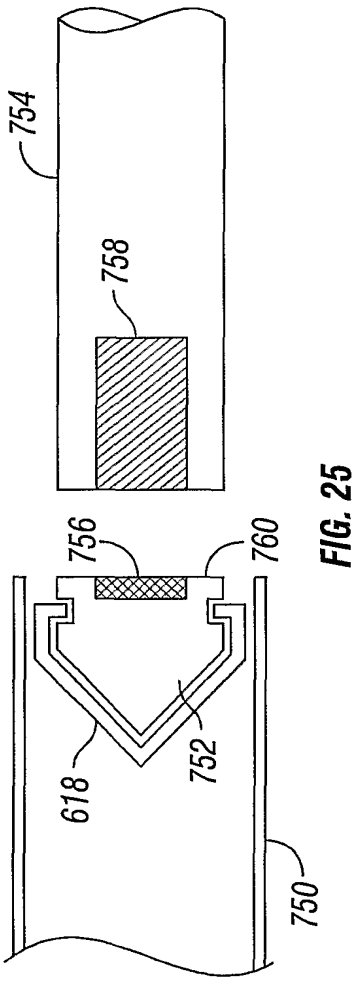
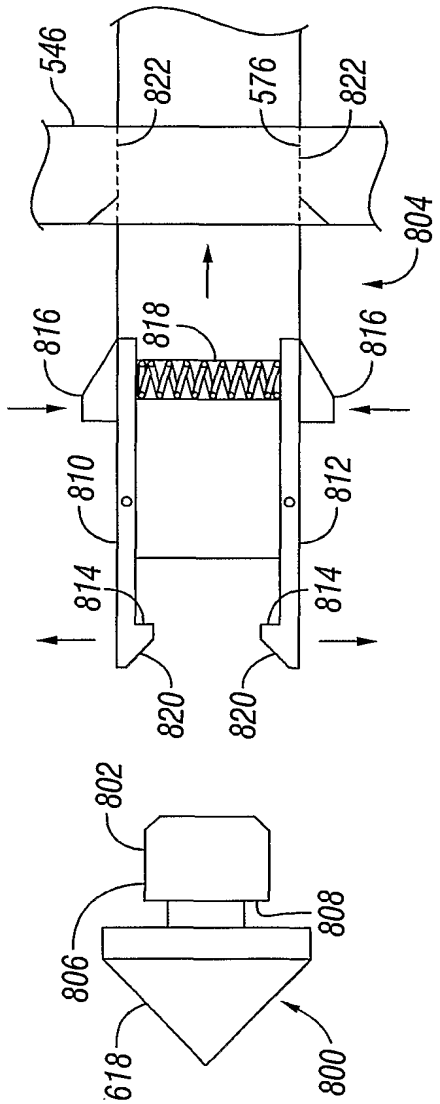

754
758
756
760
618
752
750

FIG. 25


546
822
576
822
804
816
818
816
810
812
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820
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618
800

FIG. 26

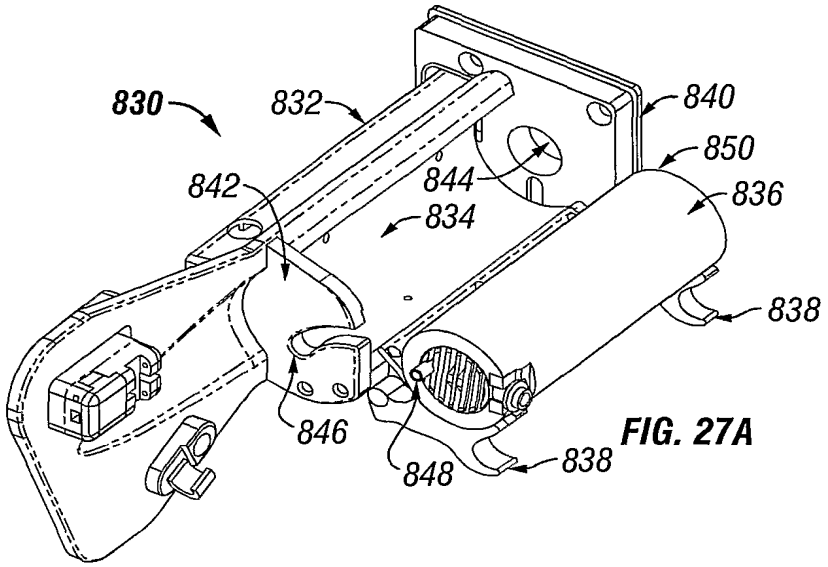

FIG. 27A

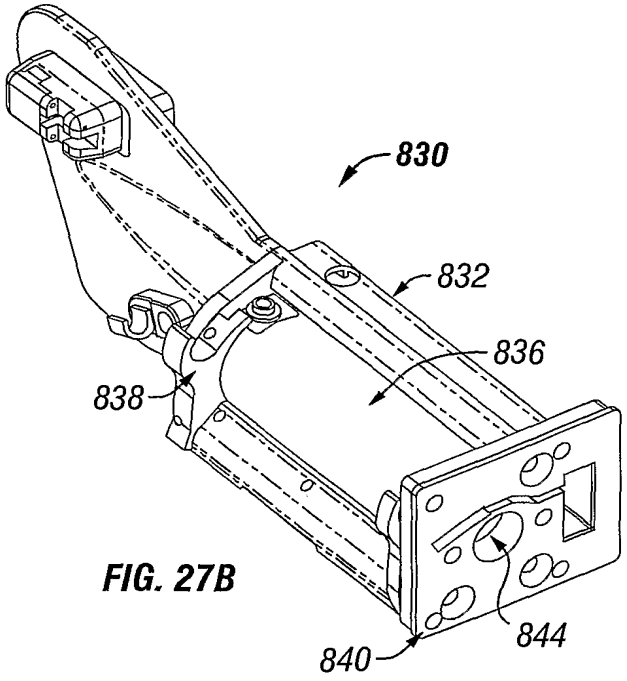

FIG. 27B

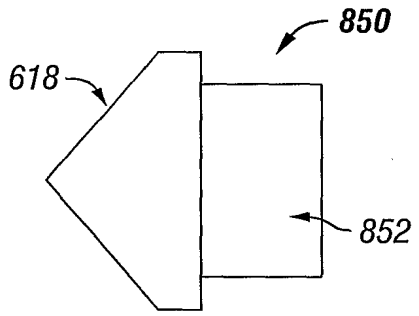

FIG. 27C

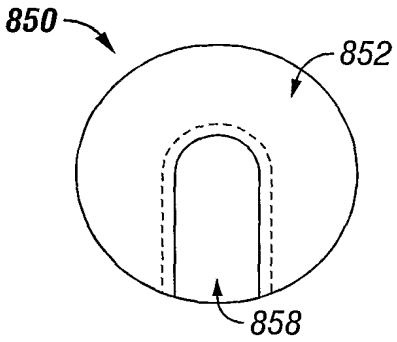

FIG. 27D

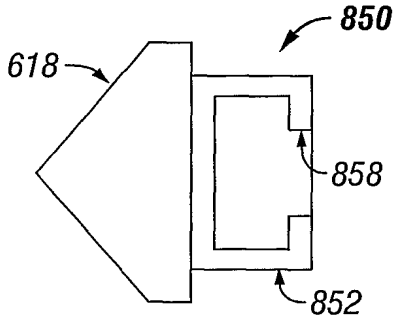

FIG. 27E

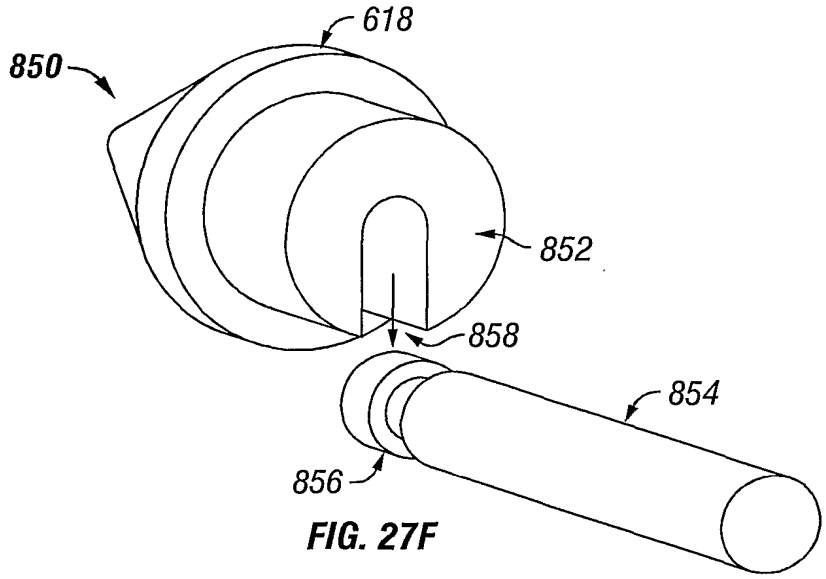

FIG. 27F

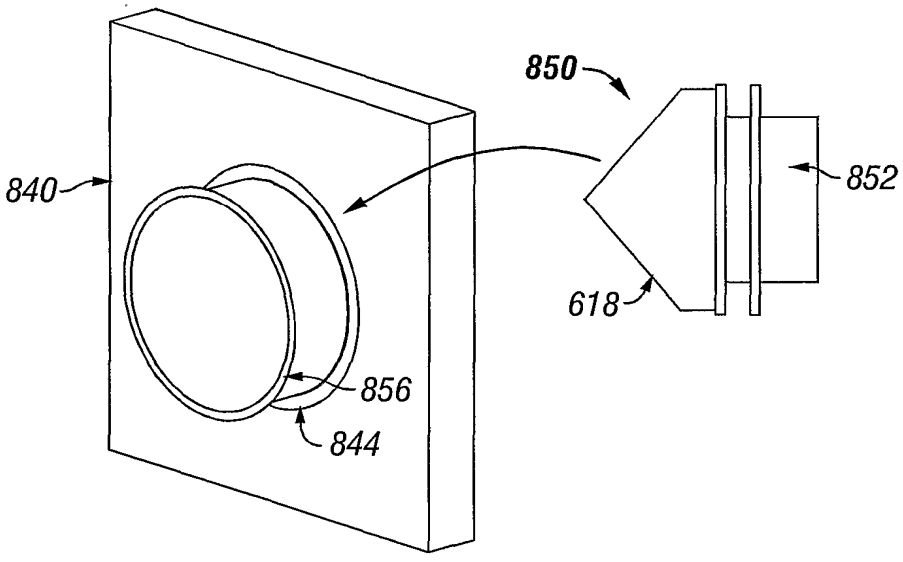

FIG. 27G

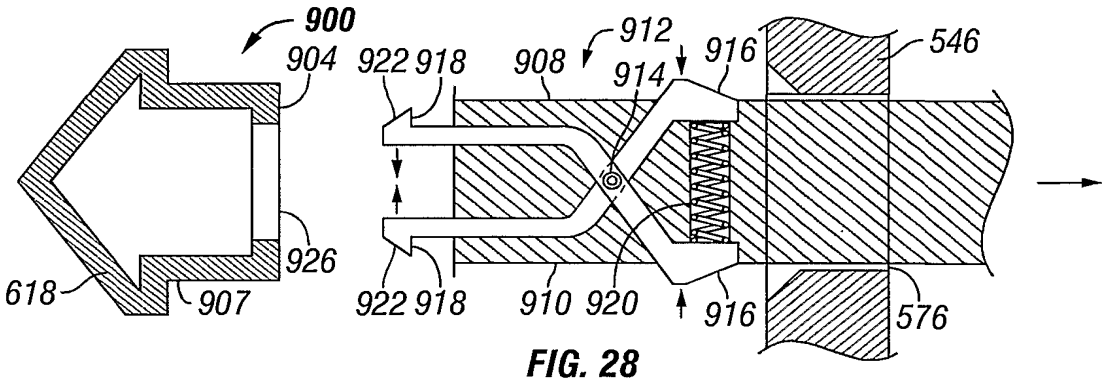

FIG. 28

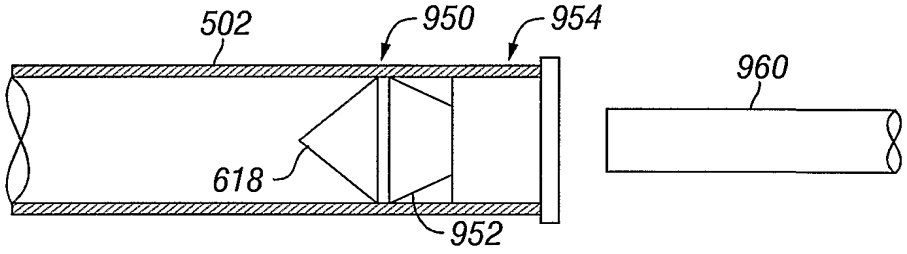

FIG. 29A

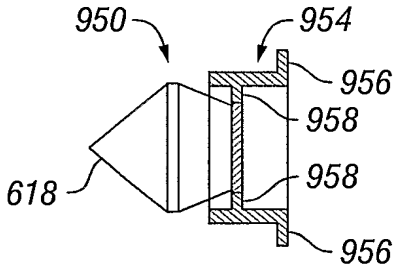

FIG. 29B

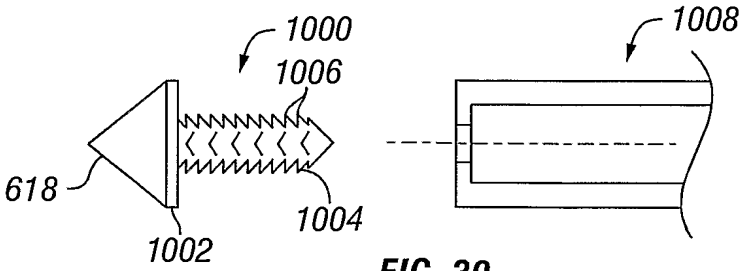

FIG. 30

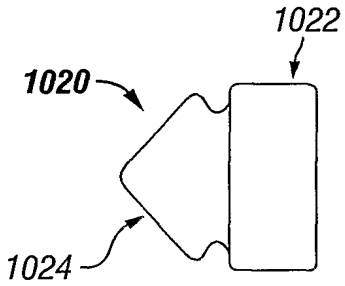

FIG. 31A

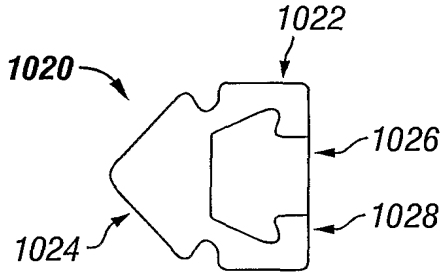

FIG. 31B

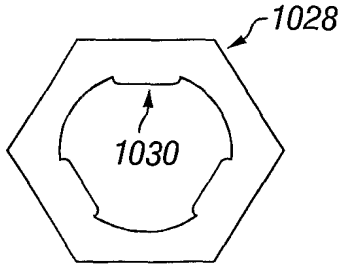

FIG. 31C

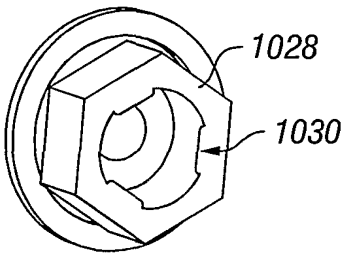

FIG. 31D

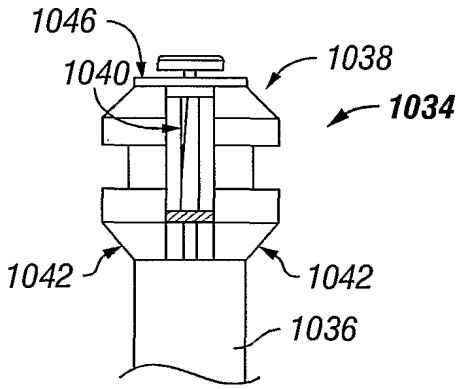

FIG. 31E

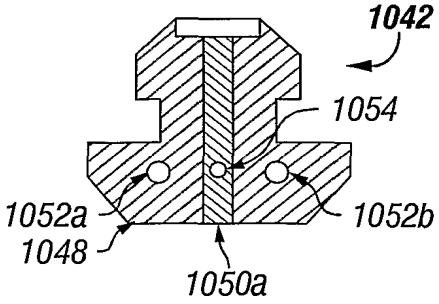

FIG. 31F

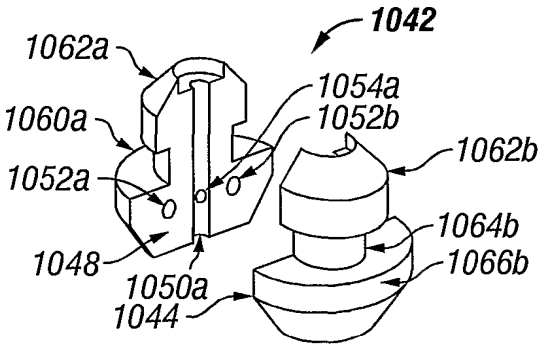

FIG. 31G

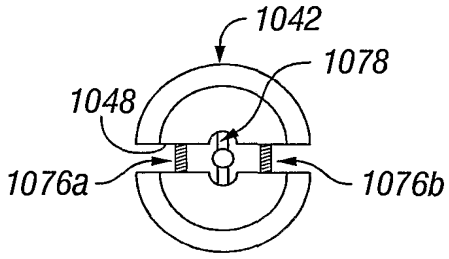

FIG. 31H

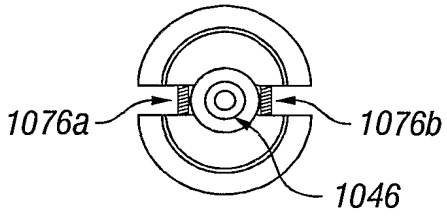

FIG. 31I

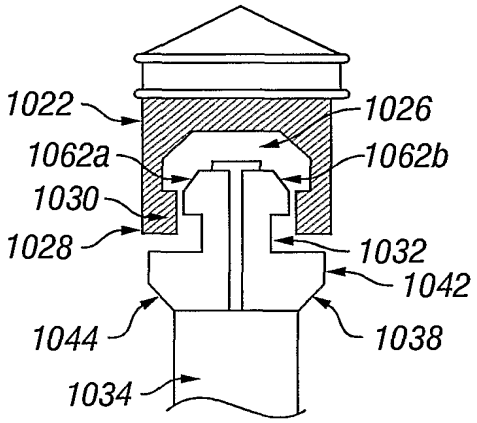

FIG. 31J

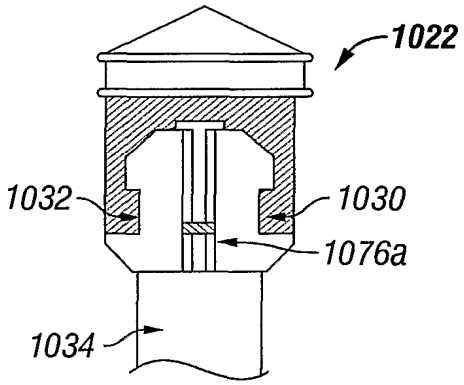

FIG. 31K

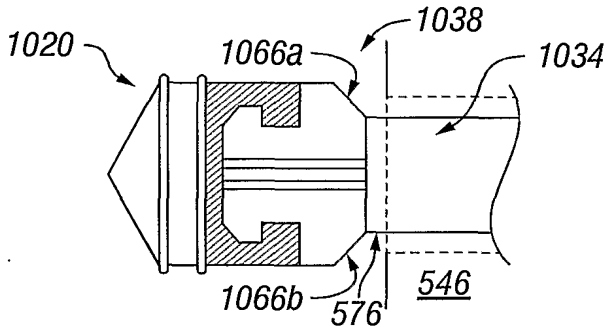

FIG. 31L

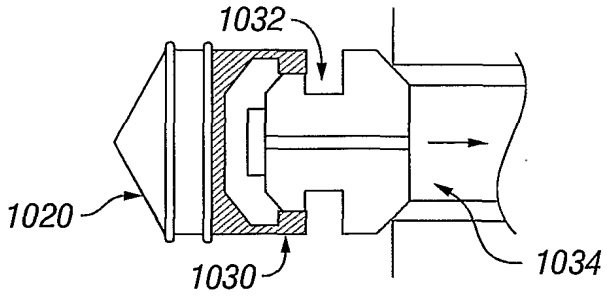

FIG. 31M